

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 1

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT			

L Apr-12-79 79-1 DRS 110128

SUBMITTED IND A FOR CL 232,315. ATTACHED: PART X
INCLUDES CLINICAL TRIAL PLAN FOR PHASE I AND EARLY
PHASE II & PROTOCOL FOR INITIAL PHASE I STUDY TO
BE CONDUCTED BY J. DURANT; PART IX INCLUDES CVs
FOR DRs. DURANT, GAMS, AND MURRAY. QUALIFICATIONS
& PROTOCOLS FOR EACH ADDITIONAL INVEST. WILL BE
FILED BEFORE STUDY BEGINS.

F May-21-79 DRS 110127

ACKNOWLEDGE RECEIPT OF IND A PERSUANT TO SECTION
505(i) AND ASSIGNMENT OF IND A NO. 16-332 FOR CL
232,315.

L Jun-01-79 79-2 DRS 110125

STUDY PROPOSED FOR DR. ARNOLD CANCELLED
(ADMINISTR. REASONS) & INITIAL STUDY TO BE
PERFORMED BY DR. D. VON HOFF. ITEMS SUBMITTED: V
REVISED QC MONOGRAPH OF CL 232,315 PARENTERAL; IX
CHECKLIST & CVs FOR VON HOFF & DR. COLTMAN; X
REVISED CLINICAL TRIAL PLAN & PROTOCOL FOR VON
HOFF'S STUDY.

F Aug-06-79 DRS 110154

REF. SUBJECT IND A, RECOMMENDATIONS & REQUESTS:
MEDICAL: APPLY RADIONUCLIDE TEST FOR CARDIAC TOX.
IN UNIV. OF TEXAS STUDY TO REPLACE CANCELLED STUDY
AT UNIV. OF ALABAMA. CHEMISTRY: 19 REQUESTS ON
SPECS. AFFECTING CONTROLS & MANUFACTURING.
PHARMACOLOGY: REQUEST ANIMAL MODELS DEMONSTRATING
COMPARATIVE CARDIOTOX. OF SUBJECT DRUG AND
DOXORUBICIN ETC., ANALOGOUS TO A CLINICAL
SITUATION.

F Sep-17-79 DRS 110129

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 2

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp	Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

re. INDA AND AMDT. OF 6/1/79. RECOMMENDATION:
RADIONUCLIDE TECH. FOR CARDIAC TOX. PROPOSED IN
CANCELLED PHASE I STUDY AT UNIV. OF ALABAMA SHOULD
BE APPLIED TO INITIAL PHASE I STUDY AT UNIV. OF
TEXAS.

L Sep-19-79

79-3 DRS 110130

RESP TO FDA LETTER (8/6/79) AND SUPPLYING
QUALIFICATIONS FOR NEW INVEST & PROTOCOL FOR HIS
STUDY. ITEMS ATTACHED: AMEND. A, RESPONSE TO CHEM.
ITEMS 1-9 (IN 8/6 LETT.); PART VI, RESPONSE TO
PHARMACOLOGY REQUEST (IN 8/6 LETT.); PART IX,
CHECKLIST & CVs FOR ALBERTS & HERMAN; PART X,
RESPONSE FOR MURRAY TO MEDICAL RECOMMEND. (IN 8/6
LETT.); PROTO. FOR ALBERTS STUDY TO INCORPORATE
CARDIAC TOX BY RADIONUCLIDE TECH.

L Nov-26-79

79-4 DRS 110131

AMENDED INDA: PART IX, CHECKLIST & CVs FOR
ADDITIONAL INVEST. A. LIPTON & ASSOCIATE DR.
HARVEY; PART X, PROTOCOL FOR LIPTON STUDY -
APPROVED BY CLINICAL INVEST. COMMITTEE. STUDY BY
D. ALBERTS SUSPENDED AT REQUEST OF DR. JOHNSON
(10/15). AFTER DISCUSSED SUPPORTING DATA, JOHNSON
AGREED TO RESUMPTION OF STUDY. E. MCKEON OF LED.
INFORMED AND STUDY NOW IN PROGRESS.

L Dec-04-79

79-5 DRS 110132

re. FDA LETTER 8/6/79 CHEMISTRY (ITEM 1); REQUEST
RELEASE SPECIFICATIONS ON RAW MATERIALS AS
SUPPLIED BY MANUFACT. AND ANY ADDIT. CONTROLS
PERFORMED BY LED. ATTACH. A, (LED. LETTER
9/19/79), INDICATED INFO. TO BE FURNISHED A.S.A.P
(INCLUDED PART V). ITEMS SUBMITTED: PART V,
AVAILABLE MANUFACT. RELEASE SPECS.; PART X,
ADDENDA TO PROTOCOL SUBMITTED 11/2/79 FOR A.
LIPTON STUDY.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 3

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

F Dec-14-79 DRS 110133

REF. INDA AND AMEND. OF 9/19 AND 11/2 AND TELE.
CONVERSATION 10/15/79 BETWEEN (LED) MURRAY AND
(AGENCY) JOHNSON AND 10/31/79 CONVERSATION BETWEEN
(UNIV. ARIZONA) ALBERTS AND JOHNSON. AGREED 10/31,
NO OBJECTION TO ALBERTS CONTINUING PHASE I STUDY
PROVIDED CLOSE CONTACT WITH VON HOFF IS KEPT
REGARDING DEVELOPMENTS IN HIS RELATED STUDY.

L Mar-04-80 80-1 DRS 110134

AMENDED INDA: PART IX, CHECKLIST AND CVS FOR J.
HOLCENBERG AND T. VIETTI, AND DRs. FUSNER, LAND &
BHANDOT; PART X, PROTOCOL FOR HOLLENBERG STUDY,
PROTOCOL FOR VIETTI STUDY, & ADDENDA TO PROTOCOL
SUBMIT. 9/19/79 FOR ALBERTS STUDY.

L Apr-30-80 80-2 DRS 110135

AMENDED INDA: PART IX, CHECKLIST OF CURRENTLY
ACTIVE INVESTIGATORS; PART X, ANNUAL PROGRESS
REPORT.

L Jun-20-80 80-3 DRS 110136

AMENDED INDA: PART IX, CVS DRs. WYNERT AND
SIMMONDS, ASSOCIATES WITH LIPTON AND STUDY FILED
10/4/79; PART X, CLINICAL REPORT FOR VON HOFF
STUDY.

L Aug-19-80 80-4 DRS 110137

AMENDED. INDA PROVIDE FOR PHASE II STUDIES.
CLINICAL TRIAL PLAN DESCRIBES ARRANGE. WITH NCI
FOR ONCOLOGY GROUP STUDIES. ITEMS INCLUDED: PART
VI, ADDITIONAL PRECLINICAL STUDIES; PART VII,
UPDATED INVEST BROCHURE; PART IX, UPDATED CV FOR
VON HOFF (ORIGINALLY LISTED AS AN INVEST 6/1/79);
PART X, CLINICAL TRAIL PLAN, 7 PROTOCOLS FOR PHASE
II STUDIES, CLINICAL REPORT FOR ALBERTS STUDY.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 4

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Oct-08-80		80-5	DRS	110138
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AMENDED INDA: PART I, USAN NOMENCLATURE STATEMENT; PART X, ADDENDUM TO PROTOCOL SUBMIT. 11/2/79 FOR LIPTON STUDY (EARLIER ADDENDA FILED 12/4/79). ALSO, TAYLOR PHARMACAL CO., ILL. CONTRACTED TO MANUFACT. & PACKAGE CL 232,315 FOR LED. EXHIBIT I, MANUFACT. & CONTROL DOCUMENT. & GMP STATEMENT. BOTTLES & FINISHED STOCK TO LED. FOR QC RELEASE TEST PRIOR TO CLINICAL TRIAL.

L Oct-22-80		80-6	DRS	110139
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AMENDED INDA: PART IX, CVs DRs. BERGAMINI AND SEDLIS TO ASSIST T. VIETTI; PART X, AMEND. TO PROTOCOL SUBMIT. 3/4/80 FOR HOLCENBERG STUDY.

L Nov-13-80		80-7	DRS	110140
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AMENDED INDA: PART IX, UPDATED CV FOR D. ALBERTS & CVs FOR DRs. WOOLFENDA, PATTON AND AAPRO TO ASSIST ALBERTS; PART X, PROTOCOL FOR ALBERTS NEW STUDY. PROTOCOL AMEND. FILED 10/22/80 FOR HOLCENBERG STUDY ALSO APPLIES TO VIETTI STUDY SUBMIT. 3/4/80.

L Nov-24-80		80-8	DRS	110141
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AMENDED INDA: PART IX, CHECKLISTS AND CVs FOR 27 ADDITIONAL INVEST., UPDATED CV FOR VON HOFF. ALL INVESTIGATORS WILL FOLLOW 7 PHASE II PROTOCOLS SUBMIT. 8/19/80 AND WILL REPORT THROUGH VON HOFF.

L Dec-16-80		80-9	DRS	110142
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AMENDED INDA: PART X, TWO ADDITIONAL PROTOCOLS FOR PHASE II STUDIES AND REPORTED THROUGH VON HOFF. MEMBERS OF GROUP NAMED IN SUBMISSION OF 8/19/80 AND 11/24/80.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 5

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
------------------------	-------------------	-------------	--------------------------	---------	----------------------------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Feb-06-81 81-1 DRS 110143

AMENDED INDA: PART III, FORMULAS; PART VII, LABELS; PART X, ADDITIONAL PROTOCOL FOR PHASE II STUDIES, AND REPORTED THROUGH VON HOFF. MEMBERS OF GROUP NAMED IN SUBMISSION OF 8/19/80 AND 11/24/80, AMEND. TO PROTOCOL FOR HOLCENBERH & VIETTI SUBMIT. 3/4/80 AND AMENDED 10/22/80.

L Mar-31-81 81-2 DRS 110144

AMEND INDA: PART III, FORMULA; PART IV, SYNTHESIS RADIOLABELED MITOK.; PART VII, LABELING; PART IX, CHECKLIST SHOWING 3rd STUDY BY ALBERTS (QUALIFICATION SUBMIT 11/13/80), CHECKLISTS 21 ADDIT. INVEST & THEIR CVs, CV FOR DAVIS (ASSOCIATE ALBERTS); PART X, PROTOCOL ALBERTS NEW STUDY, 10 PROTOCOLS FOR PHASE II STUDIES, RESULTS REPORTED THROUGH GAMS, 3 PROTO. FOR PHASE II AND REPORT THROUGH VON HOFF, CLINICAL REPORT FOR LIPTON STUDY.

L Apr-10-81 81-3 DRS 110145

AMENDED INDA: PART V, ADDIT. STABILITY DATA; PART IX, CHECKLIST FOR ADDITIONAL INVEST. J. ALLEGRA, AND REPORTED THROUGH GAMS, REVISED CHECKLIST NAMING D. WOODWARD MONITOR FOR ALBERTS STUDY SUBMITTED 3/31/81, CV FOR ALLEGRA AND WOODWARD.

L Jun-02-81 81-4 DRS 110146

AMENDED INDA: PART IX, CHECKLIST OF CURRENT ACTIVE INVEST., CV FOR T. TERZAKIS; PART X, ANNUAL PROGRESS REPORT, AMEND. TO VON HOFF PHASE I STUDY (SUBMIT. 6/1/79), VON HOFF STUDY REPORT.

L Jun-08-81 81-5 DRS 110147

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 6

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

AMENDED INDA: PART IX, CHECKLIST AND CV FOR ADDITIONAL INVEST. J. NEIHART AND CVs FOR ASSOCIATES DRs. MISER AND MALSPEIS; PART X, PROTOCOL FOR NEIDHART STUDY, AMEND. TO HOLCENBERG AND VIETTI STUDIES SUBMIT. 3/4/80 AND AMENDED 10/22/80 AND 2/6/81.

L Jul-08-81

81-6 DRS 110148

AMEND INDA: PART VII, UPDATE BROCHURE FOR INVEST, SAMPLE LETTER WITH ATTACH FROM LEV DESCRIBING INCIDENTS OF CARDIOTOX IN PATS TREATED WITH MITOX. LETTER SENT TO ALL LED INVEST & NCI NOTIFIED BY LEV; PART IX, UPDATED CV VIETTI; PART X, AMEND TO PROTOCOL FOR HOLCENBERG & VIETTI STUDIES SUBMIT 3/4/80 & AMEND 10/22/80, 2/6 & 6/8/81, PROT FOR PHASE II STUDY BY POG, HOLCENBERG & VIETTI COMBINE CLIN REP, ADDENDUM LIPTON REP SUBMIT 3/31/81.

L Jul-31-81

81-7 DRS 110151

AMENDED INDA: PART VI, ADDIT. PRECLINICAL STUDIES; PART VII, SAMPLE LETTER WITH ATTACH. FROM LEV SUMMARIZING 9 CASES OF CARDIOTOX. ASSOCIATED WITH MITOX. & LISTING NEW ENROLL. RESTRICTIONS - SENT TO ALL LED. INVEST.; PART IX, CVs FOR DRs. BERGAMINI, DISTELHORST, LAND, & SEDLIS (ASSOC. TERESA); PART X, REPORT OF AN ADVERSE EXPERIENCE (ONE DESCRIBED IN LEV'S LETTER 7/14/81).

L Sep-08-81

81-8 DRS 110149

AMENDED INDA: PART X, PROTOCOL AMEND. TO ONGOING MITOXANTRONE STUDIES INITIATED BY NCI DUE TO REPORTS OF CARDIOTOX., REPORT OF AN ADVERSE EXPERIENCE.

L Oct-23-81

81-9 DRS 110157

AMENDED INDA: PART X, AMEND. TO PROTOCOL SUBMIT. 3/31/81 FOR ALBERTS STUDY.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 7

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

F Oct-26-81 DRS 110152

REF. INDA: REPORTED 20 CASES CONGESTIVE HEART FAILURES IN PAT. RECEIVING MITOX. REQUIRING A COMPREHENSIVE PLAN FOR FUTURE STUDIES. THIS SUBMISSION SHOULD ACT AS INTERIM PROGRESS REPORT TO INCLUDE TOTAL NO. PAT. ENTERED TO DATE, TUMOR RESPONSE & TYPE OF DOSE SCHED., LIST ALL STUDIES & WHICH STILL OPEN, & INFO. ON TOX. i.e. MOST FREQUENTLY SEEN AND PERCENT OF PAT. OCCUR. REQUEST ALSO BEING MADE OF NCI.

L Nov-30-81 81-10 DRS 110153

RESPONSE TO FDA CORRES. 10/26/81 REGARDING EFFICACY AND SAFETY OF MITOX. ATTACHED REPORT ID'S SOURCES OF DATA AND NO. PATS. INVOLVED. MORE DETAILED REPORT TO BE SUPPLIED BY JANUARY. DRs. ALBERTS AND NEIDHART STUDIES ARE CURRENTLY ACTIVE.

L Dec-30-81 81-11 DRS 110150

AMENDED INDA: PART V, QC MONOGRAPH & RELATED ANALYT. RESEARCH METHOD REPORT 78, UPDATE HPLC ASSAY BULK DRUG SUBSTANCE & PARENT. PREPS.; PART IX, CV & CHECKLIST FOR D. McDONALD, CV FOR R. FOWLER (ASSIST. McDONALD); PART X, PROTOCOL FOR 2 STUDIES BY McDONALD, PROTOCOL FOR PHASE II-III STUDY CONDUCTED BY SWOG & REPORTED THROUGH VON HOFF, AMEND TO PREVIOUS SUBMIT. SWOG PROTOCOLS.

L Mar-04-82 82-1 DRS 110155

AMENDED INDA: PART IX, CHECKLIST AND CV FOR ADDITIONAL INVEST. J. STURGEON; PART X, PROTOCOL AND CRF FOR STURGEON STUDY, REPORT OF ADVERSE EXPERIENCE IN NCI-SPONSORED STUDY.

L Mar-17-82 82-2 DRS 110156

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 8

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

AMENDED INDA: PART IX, CV M. FUJIMORI TO MONITOR STUDIES PREVIOUSLY ASSIGNED TO MURRAY OR TERZAKIS. WOODWARD & FOWLER CONTINUE TO MONITOR STUDIES INDICATED ON CHECKLIST AT TIME OF PROTOCOL FILING.

L Mar-26-82 82-3 DRS 110158

REF. FDA CORRES. 10/26/81 AND LED. RESPONSE 11/30/81. REPORT SUMMARIZ. SAFETY & EFFICACY DATA FOR MITOX. SUBMITTED. ITEMS ATTACHED: PART X, MITOX. REPORT, PROPOSED CLIN. OPERATING PLAN, DRUG EXPERIENCE REP. FROM ALBERTS CARDIAC FUNCT. STUDY (LED. SPONSOR), DRUG EXPERIENCE REP. FROM PAT. IN NCI-SPONSORED STUDIES. REQUEST FOR MEETING TO DISCUSS FUTURE CLIN. STUDIES WITH MITOX.

L Apr-20-82 82-4 DRS 110159

AMENDED INDA: PART VI, ADDITIONAL PRECLINICAL STUDIES; PART X, FD FORM 1639 FILED 3/4/82 FOR PAT. B.B., #54585. DISCUSSION OF CARDIAC DIFFICULTIES AND "NOT CONTRIBUTING TO DEATH". AFTER FURTHER REVIEW, RELATIONSHIP WOULD BE CLASSIFIED AS "POSSIBLE". (SEE LETTER FOR MORE DETAILED DESCRIPTION OF CARDIAC DIFFICULTIES.)

L May-06-82 82-5 DRS 110126

AMENDED IND SUBMIT.: IX, CHECKLIST OF CURRENTLY ACTIVE INVEST.; X, ANNUAL PROGRESS REPORT.

L May-25-82 82-6 DRS 111759

IN ANTICIPATION OF 6/23/82 MEETING, SUBMIT 1)PROSPECTIVE CLINICAL OPERATING PLAN, 2)PROTOCOL FOR STUDY IN PATIENTS WITH BREAST CANCER.

L Jun-07-82 82-7 DRS 110351

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 9

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
------------------------	-------------------	-------------	--------------------------	---------------------------	----------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

AMEND. SUBJECT INDA: PART VII, REVISED BROCHURE FOR INVEST.; PART IX, CHECKLIST STUDY BY YAP (BODEY CO-INVEST.), CVs YAP & BODEY AND ASSOC. BLUMENSCHEN, EWER, BENJAMIN, HORTOBAGYI, SCHELL, AND WALLACE; PART X, PROTOCOL FOR YAP AND BODEY STUDY.

L Jun-11-82 82-8 DRS 110515

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR ROWAN & ASSISTANTS TONG & BLOCK; PART X, PROTOCOL FOR CHLEBOWSKI'S STUDY.

L Jun-14-82 82-9 DRS 110514

PURSUANT TO TELE. CONVERSATION WITH JOHNSON(FDA) 6/9/82, SENDING ADDITIONAL PROTOCOLS FOR REVIEW PRIOR TO MEETING 6/23. CALL ATTENTION TO PROTOCOL SUBMIT 6/7/82 FOR YAP & BODEY STUDY (ITEM 5 ON TABLE 1 OF PROSPECTIVE CLIN. OPERATING PLAN).

L Jul-13-82 82-10 DRS 110832

AMEND SUBJECT INDA: PART VII, PHARMACY BROCHURE; PART IX, CHECKLIST & CVs FOR SILVER LEVICK GRACE ALLEGRA WOODCOCK & WOLFF, CV FOR ASSISTS PASMANTIER COLEMAN NACHMAN JAROWSKI SOLF RUGGIERO RESNICK CHIARIERI SALETAN MOLANDER(SILVER), LEVICK DESAI(LEVICK), JOHNSTON SARG(GRACE), KUBOTA RICHMAN BLUMENREICH(ALLEGRA), & GRECO HAINSWORTH BRENNER HANDE(WOLFF); PART X, PROT & CRF FOR MULTI-CENTER STUDY, DRUG EXPERI FROM NCI STUDY.

L Jul-15-82 82-11 DRS 110827

SUBMIT TO SUBJECT INDA PACKAGE 2 DRUG EXPERIENCE REPORTS FROM NCI STUDIES OMITTED FROM 7/13/82 SUBMIT.

L Jul-22-82 82-12 DRS 111760

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 10

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR 5 NEW INVESTIGATORS & CVs FOR THEIR ASSOCIATES (REF HARD COPY LETTER FOR LIST OF NAMES); PART X, DRUG EXPERIENCE REPORT. FIVE NEW INVEST TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Jul-29-82 82-13 DRS 111062

AMEND SUBJECT INDA: CHECKLIST & CVs FOR SPICER, PERLOFF & DUGAN, CVs FOR MITCHELL, ARDALAN, BERTRAM, GRUNBERG, KEMPF, & DANIELS (ASSIST SPICER), CVs FOR ELLISON, HYMAN, OSTER, STOOPLER, & RAPOPORT (ASSIST PERLOFF), CVs FOR SCHROEDER, BATES, & WORKMAN (ASSIST DUGAN); PART X, EXPLAIN CARDIOTOX MONITOR FOR STURGEON STUDY (SUBMIT 3/4/82). 3 INVEST ABOVE TO FOLLOW PROT SUBMIT 7/13/82.

L Aug-05-82 82-14 DRS 111092

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR ROSS, CV FOR KRAMER (ASSIST ROSS). ROSS TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Aug-18-82 82-15 DRS 111185

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR MOORE, DAO & VOLBERDING, CVs FOR NEMOTO & PATEL (ASSIST DAO), CV FOR GENTILE (ASSIST ALLEGRA & WOODCOCK IN STUDY SUBMIT 7/13/82); PART X, AMEND TO PROTOCOL TO AFFECT DAO'S STUDY ONLY. ALL INVEST TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Aug-24-82 82-16 DRS 111222

AMEND SUBJECT INDA: PART IX, CHECKLIST & UPDATED CV FOR NEIDHART & CVs FOR ASSOC BALCERZAK, BOURONCLE, DEWALD, GREVER, KRAUT, METZ, RINEHART, ROACH, SOGONE, WALL, & WILSON; PART X, PROT FOR NEIDHART STUDY & SAMPLE COMPUTER CRF. SPONSOR FOR 1st NEIDHART STUDY (ON SINCE 11/80) TRANSFER FROM NCI TO LED. DETERMIN OF PHARMACOKINETIC PARAMETER DELETED FROM PROT OBJECTIVE. UPDATED TOX STUDIES INCLUDED.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 11

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Sep-03-82	82-17	DRS	111245
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AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR DOTY & GOLOMB, CVs FOR KANE & REGAN (ASSIST DOTY), CVs FOR ALBAIN, BARON, GAYNOR, HOFFMAN, LARSON, NEELY, PEARSON, ULMANN, VAN SHEPARD, & WADE (ASSIST GOLOMB). DOTY & GOLOMB TO FOLLOW PROTOCOL SUBMIT 7/13/82.

L Sep-10-82	82-18	DRS	111250
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AMEND SUBJECT INDA: PART IX, CHECKLIST FOR SILVER 2nd STUDY (QUALIF SUBMIT 7/13/82), CHECKLIST & CVs FOR ARMENTROUT, BROUN, & GOLDMAN, CVs FOR BROWER & MOORE (ASSIST SILVER), STATER (ASSIST ARMENTROUT), GALLAGHER, JOIST, D.LUEDKE, S.LUEDKE, & PETRUSKA (ASSIST BROUN), GRADY, BURNINGHAM, GALEN (ASSIST GOLDMAN); PART X, PROT TO BE FOLLOWED BY SILVER, ARMENTROUT & BROUN. GOLDMAN TO FOLLOW PROT SUBMIT 7/13/82.

L Sep-17-82	82-19	DRS	111277
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AMEND SUBJECT INDA: PART IX, CHECKLIST FOR COSTANZI 2nd STUDY, CHECKLIST & CV FOR ERSLEV, UPDATED CV FOR COSTANZI, CHECKLIST FOR BLOCK (QUALIF FILED 6/11/82), CVs FOR ALPERIN GARDNER, GUPTA, & WEISS (ASSIST COSTANZI), CVs FOR 10 ERSLEV'S ASSOCIATES (SEE HARD COPY FOR NAMES). BLOCK TO FOLLOW PROT SUBMIT 7/13/82. COSTANZI & ERSLEV FOLLOW PROT SUBMIT 9/10/82.

L Sep-29-82	82-20	DRS	111320
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REF SUBJECT INDA; SUBMIT NOTED FROM 6/23/82 MEETING WITH FDA.

L Oct-01-82	82-21	DRS	111323
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REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 12

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp	Event ----- Due ID
------------------------	-------------------	-------------	--------------------------	--------------	--------------------------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR
ARLIN & CVS FOR ASSIST CLARKSON, GEE, KEMPKIN,
MERTELSMANN, & STRAUS. ARLIN TO FOLLOW PROTOCOL
SUBMIT 9/10/82.

L Oct-07-82 82-22 DRS 111347

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVS FOR
WHITE, BITRAN, & AMARE, CVS FOR BILLINGS, DESSER,
KOSLOFF, NEWMAN, ROBIN, SHAPIRO, & SWEET (ASSIST
BITRAN), CVS FOR BODENSTEINER, COOK, LYNCH, &
SKIKNE (ASSIST AMARE); PART X, AMEND TO PROT
FOLLOWED BY SILVER, ALLEGRA, WOODCOCK, & PERLOFF.
WHITE & BRITTAN TO FOLLOW PROT SUBMIT 7/13/82,
AMAR FOLLOW PROT SUBMIT 9/10/82.

L Oct-18-82 82-23 DRS 111358

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVS FOR
STARLING, MISER, MULNE, & MILLER, CV FOR FERNBACH,
MAHONEY & STEUBER (ASSIST STARLING), CV FOR
NEWTON, ROACH & RUYMANN (ASSIST MISER & MULNE), CV
FOR HOFFMAN & TAN (ASSIST MILLER); PROTOCOL & CRF
FOR MULTICENTER STUDY.

L Oct-25-82 82-24 DRS 111368

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR
ADDITIONAL STUDY BY GAMS, CHECKLIST & CV FOR
CASSELETH AND VATS, CV FOR THUEWORTHY (ASSIST
VATS), UPDATED CV FOR GAMS. GAMS & CASSILETH TO
FOLLOW PROTOCOL SUBMIT 9/10/82. VATS TO FOLLOW
PROTOCOL SUBMIT 10/18/82.

L Nov-08-82 82-25 DRS 111402

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR 2nd
MOORE STUDY (QUALIF SUBMIT 9/18/82); PART X, AMEND
TO NEIDHART PROTOCOL SUBMIT 8/24/82, DER FOR BOTH
LED AND NCI SPONSORED STUDIES. MOORE TO FOLLOW
PROTOCOL SUBMIT 9/10/82.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 13

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Dec-03-82			82-26	DRS	111461
		AMEND SUBJECT INDA: PART IX, CV FOR BERNHARDT (ASSIST SILVER); PART X, ADDENDUM TO PROTOCOL SUBMITTED 7/13/82.			
L Dec-08-82			82-27	DRS	111465
		AMEND SUBJECT INDA: PART IX, CHECKLIST & CVS FOR PETERSON & STEIN, CVS FOR BARNES, BLOOMFIELD, HRUSHESKY, HURD, KENNEDY, KENYON, AND KIANG (PETERSON ASSOC); PART X, PROTOCOL TO BE FOLLOWED BY PETERSON & STEIN.			
L Dec-13-82			82-28	DRS	111445
		AMEND SUBJECT INDA: PART IX, CV FOR DUKART TO REPLACE FUJIMORI AS LED MONITOR; PART X, AMEND TO PROTOCOL SUBMITTED 6/7/82.			
F Dec-29-82		TELEPHONE CALL DR.JOHNSON TO DR.B.J.CLARK (CONF 1/10/83)	DRS		830034
	(a)	PROTOCOL Questioned 1st line therapy for non-Hodgkins lymph			
L Jan-04-83		AMENDMENT	83-1	DRS	830163
	(a)	CV,CKLST PT9 /003-046-006 DP3-46 SUBM 12/8/82, AMENDED 6/21/83 GAMS,RICHARD A LYMPHOMA NON-HODGKIN'S			
		AMEND SUBJECT INDA: PART IX, CHECKLIST & UPDATED CV FOR GAMS. GAMS TO FOLLOW PROTOCOL SUBMITTED 12/8/82.			
L Jan-10-83	F Dec-29-82	AMENDMENT RIVKIN STUDIES	83-2	DRS	830021

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 14

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

- (a) CV & CKLST
PT9 /003-046-001
Updated
RIVKIN, SAUL E
LYMPHOMA
NON-HODGKIN'S
- (b) CV
PT9 /003-046-001
Assoc: Drs. Godman, Kaplan, Wasserman, Weber
- (c) PROTOCOL
PT10 /003-046-001
Amend re eligibility, radiotherapy, wbc before next
RX course
- (d) PROTOCOL # /PT 10 F
Hold admit pts w/non-Hodgkins lymphoma until appr

AMEND SUBJECT INDA: PART IX, CHECKLIST AND UPDATED
CV FOR RIVKIN & CV FOR ASSOCIATE GOODMAN, KAPLAN,
WASSERMAN, & WEBER; PART X, AMEND TP PROT SUBMIT
7/13/82. RIVKIN TO FOLLOW PROTOCOL SUBMIT 10/8/82.

I Jan-25-83

AMENDMENT 83-3 DRS 830071
COSTANZI/GOLOMB/JONES/CASE/SCHWARTZ/STUART STUDIES

- (a) CV(& ASSOCs), CKLST
PT9c, f /003-044-011
DP 3-44 SUBM 9/10/82
SCHWARTZ, I ROBERT
LEUKEMIA
- (b) CV(& ASSOCs), CKLST
PT9c, g /003-046-005
DP 3-46 SUBM 12/8/82
- (c) CV, CKLST
PT9c /003-046-009
DP 3-46 SUBM 12/8/82
- (d) CKLST
PT9a /003-046-008
DP 3-46 SUBM 12/8/82; COSTANZI'S CV (& ASSOCs) SUBM
9/17/82
COSTANZI, JOHN J
LYMPHOMA
NON-HODGKIN'S
- (e) CKLST, CV-ASSOC(s)
PT9b, d /003-046-003
DP 3-46 SUBM 12/8/82; JONES' CV SUBM 11/24/80

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 15

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		JONES,STEPHEN E LYMPHOMA NON-HODGKIN'S (f) CKLST,CV-ASSOC(s) PT9b,e /003-046-007 DP3-46 SUBM 12/8/82; GOLOMB'S CV SUBM 9/3/82 GOLOMB, HARVEY M LYMPHOMA NON-HODGKIN'S			
		AMEND SUBJECT INDA: PART IX, CHECKLIST FOR COSTANZI, JONES, & GOLOMB NEW STUDIES, CHECKLIST & CVs FOR SCHWARTZ, STUART, & CASE, CVs FOR JONES, GOLOMB, SCHWARTZ, & STUART'S ASSOCIATES (REF HARD COPY LETTER FOR NAMES).			
[L] Jan-31-83	[L] Sep-10-82	AMENDMENT ADDITIONAL INVESTIGATOR	83-4	DRS	830105
		(a) CV,CKLST PT9 /003-044-012 DP3-44 SUBM 9/10/82 SARTIANO,GEORGE P LEUKEMIA			
		(b) CV # /PT 9 Assoc:Drs.Babcock,Butler,Gonzalez,McFarland			
		(c) CV # /PT 9 Assoc:Drs.Puckett,Smith,Valdivieso			
		AMEND SUBJECT INDA: PART IX, CHECKLIST AND CV FOR SARTIANO, CVs FOR ASSOCIATES BABCOCK, BUTLER, GONZALEZ, McFARLAND, PUCKETT, SMITH, & VALDIVIESO. SARTIANO TO FOLLOW PROTOCOL SUBMIT 9/10/82.			
[L] Feb-03-83		AMENDMENT SILVER M.C. NON-HODGKINS LYMPHOMA;M.C. ADULT ACUTE LEUKEMIA	83-5	DRS	830132
		(a) CKLST,CV-ASSOC(s) PT9 /003-046-010 DP3-46 SUBM 12/8/82, AMND 6/21/83; SILVER'S CV SUBM 7/13/82 SILVER,RICHARD T LYMPHOMA NON-HODGKIN'S			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 16

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
------------------------	-------------------	-------------	--------------------------	---------	----------------------------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

- (b) PROTOCOL
PT10 /003-046-010
No patients on 1st line therapy
- (c) PROTOCOL # /PT 10
DP 3-44 dosage amended, originally submitted
9/10/82

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR SILVER
THIRD STUDY, CV FOR 2 ADDITIONAL ASSOCIATES MOORE
AND WOLF; PART X, AMEND TO PROT SUBMIT 9/10/82.
SILVER TO FOLLOW PROT SUBMIT 10/8/82.

F Feb-04-83

DRS 830135
6/7/82 MESTASTIC BREAST CA; 12/8/82 NON-HODGKINS
LYMPH SUBMIS

- (a) PROTOCOL
Exclude Novantrone as single agent w/non-Hodg lymph
- (b) INVEST BROCH
2/82, pg116: clar elig, monit prior heart
dis, cardiomyopathy

REF APPLICATION FOR INDA & LED CORRES 6/7 &
12/8/82. APPROVE INITIATION OF CLIN TRIALS. HAVE
FOLLOWING RECOMMENDATIONS: (1) IN PROT SUBMIT
12/8/82, SHOULD MODIFY TO EXCLUDE AS FIRST LINE
THERAPY, PAT WITH NON-HODGKINS LYMPHOMA, AND
(2) CLINICAL BROCHURE SHOULD STATE ELIGIBILITY
RESTRICTIONS REGARDING PRIOR HEART DISEASE.

L Feb-09-83

AMENDMENT 83-6 DRS 830130
SARTIANO/BODEY STUDIES

- (a) CV(& ASSOCs), CKLST, PROT
PT9,10 /003-047-001
BODEY, GERALD P
- (c) CKLST, CV-ASSOC(s) /003-040-0
PROT SUBM 7/13/82
SARTIANO, GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR 2ND
SARTIANO STUDY, CHECKLIST FOR NEW BODEY STUDY.
UPDATED CV FOR BABCOCK (ASSOCIATE OF SARTIANO).
CVs FOR BURGESS, ESTEVY, LEGHA, & VALDIVIESO
(ASSIST BODEY); PART X, PROTOCOL FOR BODEY STUDY.
SARTIANO TO FOLLOW PROTOCOL SUBMIT 7/13/82 AND
AMENDED 1/10/83.

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ----- Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					

I Feb-14-83		AMENDMENT KREMENTZ/VOGEL/HOLLAND/PLOTKIN/MUGGIA STUDIES	83-7	DRS	830124		
	(a)	CKLST & PROTOCOL PT9,10 KREMENTZ,EDWARD T CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU	/003-048-004				
	(b)	CV,CKLST,PROTOCOL PT9,10 HOLLAND,JAMES F ALL COMBINED w/ VINCERISTINE & DEXAMETHASONE	/003-055-001				
	(c)	CV,CKLST,PROTOCOL PT9,10 MUGGIA,FRANCO CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU	/003-048-001				
	(d)	CV,CKLST,PROTOCOL PT9,10 PLOTKIN,DAVID CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU	/003-048-005				
	(e)	CV,CKLST,PROTOCOL PT9,10 VOGEL,CHARLES L CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU	/003-048-002				
	(f)	CV # /PT 9 Assoc:Dr.Wang					
	(g)	CV # /PT 9 Assoc:Drs.Cuttner,Harris,Ohnuma,Paciucci					
	(h)	CV # /PT 9 Assoc:Drs.Carter,Sutherland					
	(i)	CV # /PT 9 Assoc:Drs.Blum,Bottino,Green,Levin,Speyer,Spiegel, Wernz					

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR
DREMENTZ SECOND STUDY, CHECKLIST & CVs FOR BOGEL,
HOLLAND, PLOTKIN, AND MUGGIA, UPDATED CV FOR
CARTER & SUTHERLAND, CVs FOR VOGEL, HOLLAND &
MUGGIA ASSOCIATES (SEE HARD COPY FOR NAMES); PART
X, PROT FOR VOGEL, KREMENTZ, PLOTKIN, & MUGGIA
STUDIES, PROT FOR HOLLAND STUDY.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 18

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Feb-24-83 83-8 DRS 111629

AMEND SUBJECT INDA: PART IX, CHECKLIST AND CVs FOR BYRNE & JUSS, CV FOR WOOLLEY (ASSIST BYRNE), CVs FOR PASCHOLD, CAPONERA & POPE (ASSIST MUSS), CV FOR BRAICH (ASSIST JONES IN STUDY SUBMIT 1/25/83). BYRNE & MUSS TO FOLLOW PROTOCOL SUBMIT 2/14/83.

L Mar-02-83 83-9 DRS 111663

AMEND SUBJECT INDA: PART IX, CHECKLIST & CV FOR DESAI, CV FOR DIMITROV TO ASSIST NEIDHART. DESAI WILL FOLLOW PROTOCOL SUBMIT 2/14/83. MULNE WILL BE ASSUMING RESPONSIBILITY FOR PROTOCOL STUDY SUBMIT 10/18/82 FOR MISER.

L Mar-04-83 83-10 DRS 111664

AMEND SUBJECT INDA: PART IX, CVs FOR BODEY'S ASSISTANTS ON STUDY PROTOCOL SUBMIT 2/9/83 (REF HARD COPY LETTER FOR NAMES).

L Mar-07-83 83-11 DRS 111666

AMEND SUBJECT INDA: PART IS, CHECKLIST & CVs FOR DECONTI & BRODOVSKY, CVs FOR BYRNE, DAVIS, FLATOW, HETZEL, ROSS, STEINGART, & WHITE (ASSIST DECONTI), CVs FOR LAUCIUS & HOLROYDE (ASSIST BRODOVSKY). DECONTI & BRODOVSKY TO FOLLOW PROTOCOL SUBMIT 2/14/83.

L Mar-17-83 83-12 DRS 111690

AMEND SUBJECT INDA: PART IX, CHECKLIST FOR 3rd GOLOMB STUDY, CHECKLIST & CV FOR PAPISH & ASSOCIATES KRITZMAN, MIER, MILLER, PARKINSON, RUDDERS, & TAYLOR, CV FOR LESTER & VOGELZANG (ASSIST GOLOMB). GOLOMB & PAPISH TO FOLLOW PROTOCOL SUBMIT 2/14/83. ACKNOWL RECEIPT FDA 2/4/83 LETTER AND IMPLEMENTING RECOMMENDATIONS MADE.

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 19

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT			

L Mar-22-83 83-13 DRS 111701

AMEND SUBJECT INDA: PART IX, CHECKLIST SHOWING NEW STUDY FOR GAMS & CV FOR ASSOCIATES PERLMAN AND KARDINAL. GAMS TO FOLLOW PROTOCOL SUBMIT 2/14/83.

L Mar-31-83 83-14 DRS 111715

AMEND SUBJECT INDA: PART IX, CHECKLIST & CVs FOR BENNETT & DOROSHOW, CV FOR BAKEMEIER, CARIGNAN, & MCCUNE (ASSIST BENNETT), CV FOR BERTRAND, BROWNING, CARR, & OVERBY (ASSIST DOROSHOW), CHECKLIST SHOWING ADDRESS CHANGE FOR ARLIN, UPDATED CV FOR ARLIN. BENNETT & DOROSHOW TO FOLLOW PROTOCOL SUBMIT 2/14/83.

L Apr-06-83 83-15 DRS 111750

AMEND SUBJECT ANDA: PART IX, CHECKLIST FOR HOLLAND 2ND STUDY; PART X, PROTOCOL FOR HOLLAND NEW STUDY.

L Apr-22-83 AMENDMENT 83-16 DRS 830226
PROTOCOL SUPPLEMENT TO GAM'S STUDY IN ADULT LEUKEMIA

AMEND SUBJECT INDA: PART X, PROTOCOL SUPPLEMENT TO GAM STUDY SUBMIT 9/10/82.

L May-11-83 AMENDMENT 83-17 DRS 830285
SCHEIN ASSISTING BYRNE IN STUDY FILED 2/24/83

AMEND SUBJECT INDA: PART IX, CV FOR SCHEIN TO ASSIST BYRNE IN STUDY FILED 2/24/83.

L May-27-83 AMENDMENT 83-18 DRS 830343
BERTINO/BENNETT STUDIES

L Jun-13-83 AMENDMENT 83-19 DRS 830382

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 20

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) PROG RPT & CKLST # /PT 9,10			
L Jun-15-83		AMENDMENT MULTICTR NON-HODGKIN'S LYMPH STUDY	83-20	DRS	830433
		(a) CKLST # /PT 9 ERSLEV, ALLAN J			
L Jun-21-83		AMENDMENT AMEND TO MULTICTR NON-HODGKIN'S LYMPHOMA PROTO SUB 12/8/82	83-21	DRS	830483
L Jun-24-83		AMENDMENT	83-22	DRS	830496
L Jun-29-83		AMENDMENT HENDERSON STUDY	83-23	DRS	830502
L Jul-06-83		AMENDMENT	83-24	DRS	830560
		(a) DRUG EXPER RPT # /PT 10 NCI-Sponsored Study			
L Jul-25-83		AMENDMENT	83-25	DRS	830628
		(a) CV,CKLST # /PT 9 MULTI-CENTER BREAST CANCER PROTOCOL SUBMT'D 2/14/83 MORGAN, LEE ROY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
L Jul-29-83		AMENDMENT CV'S VARIOUS ASSTS; HOLLAND STUDY	83-26	DRS	830635
		(a) PROTOCOL PT 9,10 /003-065-001 HOLLAND, JAMES F LYMPHOMA COMBINED w/ VINCERISTINE & DEXAMETHASONE			
L Aug-08-83		AMENDMENT	83-27	DRS	830645

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(a) CV & PROTOCOL # /PT 9 PROTOCOL SUBM 7/29/83 HOLLAND, JAMES F				
		(b) CV & PROTOCOL # /PT 9 7/29/83 SUBM CORRECTION: CV SUBM 3/31/83; STUDYING AC LEUKEM				
L Aug-09-83		AMENDMENT	83-28	DRS		830646
		(a) CV # /PT 9 DR GAMS' ASSISTANTS IN BREAST CA STUDY				
		(b) INVEST SITE ADDITIONAL SITE FOR AC MYELOBLASTIC LEUKEMIA STUDY WIERNIK, PETER H LEUKEMIA				
L Aug-12-83		AMENDMENT	83-29	DRS		830654
		MULTICENTER BREAST CA STUDY				
		(a) CV # /PT 9 ASS'T TO DR J. EVERETT				
L Aug-17-83		AMENDMENT	83-30	DRS		830663
		(a) CKLST /003-048-0 REPLACES DECONTI; PROT 3-48 SUBM 2/14/83; CV SUBM 3/7/83 WHITE, CHARLES F CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU				
		(b) PROTOCOL EMERGENCY TREATMENT BESIDES FORMAL STUDY				
		(d) CV-ASSOC(s) /003-048-0 test ??? MUST WE HAVE INDIVIDUAL RR6-RR7 RECORDS FOR EACH??				
L Aug-26-83		AMENDMENT	83-31	DRS		830688
		(a) PROTOCOL # /PT 10 AMEND TO AC MYELOBL LEUK PROT SUBMD 4/6/83				
		(b) PROTOCOL AMEND TO REFRACTORY LYMPHOMA STUDY SUBMITTED 7/29/83				

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 22

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-30-83		AMENDMENT	83-32	DRS	830692
	(a)	CV(& ASSOCs),CKLST PT9 /003-040-025 PROT SUBM 7/13/82, AMENDED 1/10/83 BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
L Sep-07-83		AMENDMENT	83-33	DRS	830705
	(a)	FORMULA # /PT 3 (b) MONOGRAPH # /PT 5 CONTROLS (c) STABILITY # /PT 5 (d) LABEL # /PT 7 (d) LABEL # /PT 7 (e) CV # /PT 9 ASSISTANTS TO DRS R GAMS, E KREMENTZ			
L Sep-12-83		AMENDMENT		DRS	830732
	(a)	CV CV'S FOR DR DENNETT'S ACCOCIATES			
L Sep-14-83		CORRESPONDENCE REQUEST 1-A IND/NDA CLASSIFICATION		DRS	830736
	(a)	SUMMARY NOTES FROM 5/3/83 LED-FDA MTG: MTX'S ADVNTGS OVER EXIST THER			
	(b)	SUMMARY DR CLARK PROFILE OF MTX: SAF/EFFIC IN TREATING ADV BREAST CA			
L Oct-06-83		AMENDMENT	83-36	DRS	830785
	(a)	CV # /PT 9 CV FOR DR BODEY'S NEW ASST -FORMER COINVSGTR,DR YAP, LEAVES			
L Oct-10-83		AMENDMENT	83-37	DRS	830787
	(a)	CV,CKLST CV'S FOR DR ARLIN & ASSOC'S. ADD'L ASSOC CV SUBM 3/31/83			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 23

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		ARLIN, ZALMEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
L Oct-20-83		AMENDMENT PART 10-AMNDMT TO PHASE I-II PROT (DP 3-55) SUBM 2/14/83	83-38	DRS	830815
L Oct-25-83		AMENDMENT ADD'L PRE-CLINICAL STUDIES, PART 6	83-39	DRS	830828
L Oct-28-83		AMENDMENT (a) CV, CKLST # /PT 9 CKLST FOR DR ELLISON (CV SUBM 10/6/83) & CV'S FOR HER ASSOCS (b) CV # /PT 9 DR TESTER (DR LEVICK'S ASSOC); DR GREENBERG (BLOCK'S ASSOC) (c) SUMMARY # /PT 9 DR ELLISON REPLACES DR PERLOFF (LEFT) AS PRINC INVSGTR	83-40	DRS	830840
L Oct-31-83		CORRESPONDENCE REQUEST COMMENTS ON PROSPECTIVE PROTOCOLS(2) & CLIN STRATEGY	83-41	DRS	830843
L Nov-02-83		AMENDMENT (a) CV, CKLST, PROTOCOL PT9 /003-000-000 WEINER, MARTIN J	83-42	DRS	830853
L Nov-09-83		AMENDMENT (a) PROTOCOL # /PT 10 REVISIONS (SECTNS 4.25 & 6.52) TO DR BODEY'S PROT SUB 6/7/82	83-43	DRS	830867
L Nov-11-83		AMENDMENT (a) CKLST, CV-ASSOC(s) PT9a /003-048-009 DP 3-48 SUBM 2/14/83, AMND' 2/28/84; CV SUBM 3/17/83	83-44	DRS	830875

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 24

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		PARKINSON, DAVID R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (c) PROTOCOL /003-044-0 BERTINO'S CV AND CKLST SUBM 5/27/83; ONE PT-COMPASSION BASIS BERTINO, JOSEPH LEUKEMIA			
L Nov-30-83		AMENDMENT	83-45	DRS	830903
	(a)	CKLST PT9a /003-048-017 PROT SUBM 2/14/83; CV's SUBM 7/13/82 WOLFF, STEVEN N CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU (b) CV # /PT 9b CV's FOR 3 ASSOC'S OF DR R GAMS (#34) UNDER PROT SUB 2/14/83			
L Dec-02-83		AMENDMENT	83-46	DRS	830912
	(a)	CV, CKLST, PROTOCOL PT9,10 /003-070-000 CV FOR DR JONES. HIS 3 ASSOC'S CV's WERE FILED 2/14/83 JONES, ROY CA-BREAST; DOSE RANGING ESCALATING DOSE - CARDIAC MEASUREMENTS			
L Dec-12-83		CORRESPONDENCE UPDATED CARDIOTOX RPT TO SUPPORT REQUEST FOR 1A IND/NDA CLAS	83-47	DRS	830930
L Dec-13-83		AMENDMENT	83-48	DRS	830932
	(a)	CKLST, PROT PT9a,10 /003-072-001 CV SUBM 7/22/82 HENDERSON, I CRAIG CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 25

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due	ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT				
		(b) CV,CKLST,INVEST AGREE # /PT 9b DR ARLIN(#85) TO FOLLOW THE MULTI-CTR BR CA PROT SUB 2/14/83				
L Dec-19-83		AMENDMENT	83-49	DRS		830943
		(a) CKLST # /PT 9 CL FOR DR QAZI(CV FILED 7/29/83);SUBBING FOR DR BENNETT,#111				
L Jan-04-84		AMENDMENT	84-1	DRS		831034
		(a) CV # /PT 9 CVs FOR 2 ASSOCs OF DR BERTINO (#113) FOR PROT SUBM 11/11/83				
L Jan-20-84		AMENDMENT	84-2	DRS		831068
		(a) INVEST BROCH # /PT 7 ADDENDUM TO 6/7/82 BROCHURE; RE: CARDIOTOXICITY (b) CV(& ASSOCs),CKLST PT9 /003-048-019 PROTO SUBM 2/14/83 GEORGE,SEBASTIAN CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU				
F Jan-23-84		CORRESPONDENCE REQUEST INFO ON POSSIBLE CAUSES & REMEDIES OF PRECIPITATION		GRP		831073
L Jan-31-84	B Dec-21-83	CORRESPONDENCE SUMMARY/NOTES OF PRE-NDA DISCUSSION --FOR FDA REVIEW	84-3	DRS		831095
L Feb-01-84		AMENDMENT	84-4	DRS		831106
		(a) CKLST PROT SUBM 2/14/83; CV(& ASSOCs) SUBM 8/30/83 BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU	/003-048-0			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 26

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact ----- Due	Resp Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Feb-14-84		AMENDMENT	84-5	DRS	831144
		(a) CV,CKLST,INVEST AGREE # /PT 9a DR WEIDEN(#124) WILL FOLLOW MULTI-CTR BR CA PROT SUB 2/14/83			
L Feb-21-84		AMENDMENT	84-6	DRS	831156
		(a) CKLST,PROT PT9a,10 /003-071-001 CV SUBM 1/25/83 CASE,DELVYN C LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(b) CKLST,PROT PT9a,10 /003-074-001 CV SUBM 1/25/83 CASE,DELVYN C ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Feb-22-84		AMENDMENT	84-7	DRS	831160
		(a) DEAR INVESTIGATOR LETTER # /PT 7 WARNING TO READ LABELS CAREFULLY; OD(DEATHS) AT FOREIGN HOSP			
		(b) DEAR PHARMACIST LETTER # /PT 7 WARNING TO READ LABELS CAREFULLY; OD(DEATHS) AT FOREIGN HOSP			
		(c) CV,CKLST,PROTO PT9,10 /003-075-001 UPDATED CV ALBERTS,DAVID S CA-OV,COLON; DOSE RANGING PK OF IP ADMINISTRATION			
F Feb-23-84	L Feb-23-84	ADVERTISING	ECM		831163
		TORONTO TELECONFERENCE SEEN AS PROMOTION OF UNAPPROVED DRUG			
L Feb-28-84		AMENDMENT	84-8	DRS	831166
		(a) CV,CKLST,INVEST AGREE # /PT 9a,c DR CONRAD(#125) WILL FOLLOW MULT-CTR BR CA PROT SUBM 2/14/83			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 27

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		(b) CV,CKLST,INVEST AGREE # /PT 9b,c DR CHLEBOWSKI(#60;2nd STUDY) TO FOLL ADV BR CA PROT 12/13/83					
		(c) PROTOCOL AMNDMT TO MULTI-CTR CR CA PROT SUBM 2/14/83					
L Mar-05-84		AMENDMENT	84-9	DRS			831266
		(a) CKLST PT9a /003-071-003 PROT SUBM 2/21/84; CV SUBM 10/10/83 ARLIN,ZALMEN A LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		(b) CKLST PT9a /003-074-002 PROT SUBM 2/21/84; CV SUBM 10/10/83 ARLIN,ZALMEN A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)					
L Mar-20-84		AMENDMENT	84-10	DRS			831289
		(a) CV,CKLST PT9a /003-071-002 DP 3-71 SUBM 2/21/84 MABRY,R JAMES LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		(b) CV,CKLST PT9a /003-071-004 DP 3-71 SUBM 2/21/84 COHEN,RICHARD J LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
L Mar-21-84		AMENDMENT	84-11	DRS			831290
		(a) CV # /PT 9 CV's FOR DRs ALVAREZ & RODRIGUES, DR ARLIN-S(#85) ASSISTANTS					
L Mar-27-84		AMENDMENT	84-12	DRS			831300
		(a) CV,CKLST PT9a /003-048-024 DP 3-48 SUBM 2/14/83, AMENDED 2/28/84					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 28

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

PRESANT, CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
(b) CV, CKLST
PT9b /003-048-023
DP 3-48 SUBM 2/14/83, AMENDED 2/28/84
TRUMP, DONALD L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
(c) CV, CKLST
PT9b /003-048-025
DP 3-48 SUBM 2/14/83, AMENDED 2/28/84
DENEFRIO, JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

L Mar-30-84 AMENDMENT 84-13 DRS 831302

(a) CKLST
PT9a /003-071-008
DP 3-71 SUBM 2/21/84; CV SUBM 1/25/83
(b) CV, CKLST
PT9b /003-071-005
DP 3-71 SUBM 2/21/84
DRESDNER, DAVID M
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
(c) CV, CKLST
PT9b /003-071-007
DP 3-71 SUBM 2/21/84
BLUMING, AVRUM Z
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
(d) CV, CKLST /003-074-0
DP 3-74 SUBM 2/21/84
DRESDNER, DAVID M
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Mar-30-84 F Jan-23-84 CORRESPONDENCE 84-14 GRP 831310
BUFFERED BISULFITE-FREE FORMULA'N HAS REPLACED
FORMER FORM'N

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 29

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Apr-02-84		AMENDMENT	84-15	DRS	831334
	(a)	CKLST PT9a /003-071-006 MUL-CTR COMB REGIMEN PROT SUBM 2/21/84; CV SUBM 7/13/82 WOODCOCK, THOMAS M LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L Apr-09-84		AMENDMENT	84-16	DRS	831347
	(a)	CKLST, CV-ASSOC(s) PT9a /003-048-026 PROT SUBM 2/14/83, AMENDED 2/28/84; CV SUBM 7/13/82 GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
	(b)	PROTOCOL # /PT 10 AMNDMT TO HEPATOMA PROT SUBM 6/11/82 (DR R CHLEBOWSKI #60)			
F Apr-11-84	L Sep-14-83	NOT APPROVABLE REQUEST FOR 1A CLASSIFICATION DENIED		DRS	831351
L Apr-16-84		AMENDMENT	84-17	DRS	831360
	(a)	CV, CKLST PT9abc /003-071-012 DP 3-71 SUBM 2/21/84 ABBRUZZESE, JAMES L LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(b)	CV, CKLST PT9abc /003-071-009 DP 3-71 SUBM 2/21/84 GOODMAN, GARY E LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(c)	CV, CKLST PT9abc /003-071-013 DP 3-71 SUBM 2/21/84			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 30

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		HOLROYDE, CRISTPHER P LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(d)	CKLST PT9abc /003-071-010 DP 3-71 SUBM 2/21/84; STEIN'S (2nd STUDY) CV SUBM 12/8/82			
		STEIN, RICHARD S LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(e)	CKLST PT9abc /003-071-011 DP 3-71 SUBM 2/21/84; CV SUBM 7/13/82			
		WOLFF, STEVEN N LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L Apr-19-84		AMENDMENT	84-18	DRS	831369
	(a)	CKLST PT9a /003-072-003 3-72 SUBM 12/13/83; CV SUBM 7/13/82			
		WOODCOCK, THOMAS M CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
L Apr-23-84		AMENDMENT	84-19	DRS	831370
	(a)	CV CVs FOR 3 ASSTS OF DR D SPICER (#71)			
L Apr-30-84		AMENDMENT	84-20	DRS	831379
	(a)	CKLST PT9a /003-071-014 PROT SUBM 2/21/84; CV(& ASSOCs) SUBM 3/31/84			
		BENNETT, J/QAZI, RAMAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(b)	CV(& ASSOCs), CKLST PT9b /003-074-004 PROT SUBM 2/21/84			
		GROPPE, CARL W ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
	(c)	CV-ASSOC(s) PT9c /003-071-014 BERMAN, LEVINE, STREETER, RASSIGA			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 31

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L May-02-84		AMENDMENT	84-21	DRS	831408
	(a)	CKLST PT9 /003-071-016 PROT SUBM 2/21/84; CV SUBM 2/28/84 CONRAD, MARCEL E LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L May-04-84		AMENDMENT DR KRAKOFF REPLACES DR BODEY(#100) AS PRINCIPLE INVESTIGATOR	84-22	DRS	831415
	(a)	CV,CKLST PT9 /003-041-001 KRAKOFF REPL BODEY AS PRIN INV; DP3-41 SUBM 6/7/82 KRAKOFF, I H CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE			
	(b)	CV(& ASSOCS),CKLST PT9 /003-071-015 DP3-71 SUBM 2/21/84 SHAW, JOHN LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(c)	CV,CKLST PT9 /003-047-001 KRAKOFF REPL BODEY AS PRIN INV; DP3-47 SUBM 2/9/83 KRAKOFF, I H			
	(d)	INVESTIGATOR REPLACEMENT /003-041-0 BODEY REPLACED BY KRAKOFF BODEY, GERALD P CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE			
	(e)	INVESTIGATOR REPLACEMENT /003-047-0 BODEY REPLACED BY KRAKOFF BODEY, GERALD P			
L May-22-84		AMENDMENT	84-23	DRS	831449
	(a)	CV(& ASSOCS),CKLST PT9a,d /003-048-027 DP3-48 SUBM 2/14/83, AMND 2/28/84; UPDATED CV			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND MITOXANTRONE	CL 232,315 ANTICANCER AGENT			
		OISHI, NOBORU CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
(b)		CKLST PT9b,c /003-071-018 DP3-71 SUBM 2/21/84; CV(& ASSOCs) SUBM 9/3/82			
		DOTY, GORDON L LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
(c)		CV, CKLST PT9b,c /003-071-017 DP3-71 SUBM 2/21/84; ASSOCs' CVs SUBM 3/27/84			
		KENNEDY, PETER S LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
(d)		CV(& ASSOCs), CKLST PT9b,c /003-071-019 DP3-71 SUBM 2/21/84			
		GABRIEL, DON A LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
(e)		CV(& ASSOCs), CKLST PT9b,c /003-071-012 DP3-71 SUBM 2/21/84			
		LEVINE, JAMES D LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
(f)		CV(& ASSOCs), CKLST PT9b,c /003-071-020 DP3-71 SUBM 2/21/84			
		SCOTT, ROBERT B LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
(g)		INVESTIGATOR REPLACEMENT /003-071-0 ABBRUZZESE REPLACED BY LEVINE ABBRUZZESE, JAMES L LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L May-23-84		AMENDMENT	84-24	DRS	831463
(a)		CV, CKLST PT9a /003-000-000 DP3-48 SUBM 2/14/83, AMND 2/28/84; ONE PT, COMPASSIONATE, OL			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		SAMUELS,ARTHUR J (b) CV,CKLST PT9a /003-048-028 PROT SUBM 2/21/84 BENIGNO,BENEDICT R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		(c) CV(& ASSOCs),CKLST PT9a /003-071-021 DP 3-71 SUBM 2/21/84 FASS,LEROY LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
L May-30-84		AMENDMENT	84-25	DRS	831481
		(a) CV,CKLST PT9 /003-074-005 MULTICTR COMBO REGIMEN ACUTE NONLYMPH LEUK PROT SUBM 2/21/84 TRANUM,BILL L ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L May-31-84		AMENDMENT	84-26	DRS	831480
		(a) CKLST # /PT 9 CURRENTLY ACTIVE INVESTIGATORS (b) PROGRESS RPT # /PT 10 ALBERTS,DAVID S CA-OV,COLON; DOSE RANGING PK OF IP ADMINISTRATION ARLIN,ZALMEN A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) ARLIN,ZALMEN A LYMPHOMA; vs m-BACOD m-BNCOD COMBO BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU BERNARD,STEPHEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ----- Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		BERTINO, JOSEPH LEUKEMIA					
		CASE, DELVYN C ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)					
		CASE, DELVYN C LYMPHOMA NON-HODGKIN'S					
		CASE, DELVYN C LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		DENEFRIO, JOHN M CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)					
		CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU					
		DENEFRIO, JOHN M CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)					
		CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU					
		GAMS, RICHARD A LYMPHOMA NON-HODGKIN'S					
		GOLOMB, HARVEY M LYMPHOMA NON-HODGKIN'S					
		GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)					
		CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU					
		GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN					
		MULTI-CTR 2nd LINE PTS					
		HENDERSON, I CRAIG CA-BREAST; SPECIAL-PK					
		INFLUENCE OF HEPATIC FUNCTION					
		HOLLAND, JAMES					
		HOLLAND, JAMES F					
		ALL COMBINED w/ VINCERISTINE & DEXAMETHASONE					
		HOLLAND, JAMES F LYMPHOMA COMBINED w/ VINCERISTINE & DEXAMETHASONE					
		JONES, ROY CA-BREAST; DOSE RANGING ESCALATING DOSE - CARDIAC MEASUREMENTS					

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

JONES,STEPHEN E
LYMPHOMA
NON-HODGKIN'S
KRAKOFF,IH /BODEY
KREMENTZ,EDWARD T
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MORGAN,LEE ROY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MUGGIA,FRANCO
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PARKINSON,DAVID R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PLOTKIN,DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PRESANT,CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
RIVKIN,SAUL E
LYMPHOMA
NON-HODGKIN'S
SCHWARTZ,I ROBERT
LEUKEMIA

SEBASTIAN,GEORGE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
SILVER,RICHARD T
LYMPHOMA
NON-HODGKIN'S
STUART,JOHN J
LYMPHOMA
NON-HODGKIN'S
TRUMP,DONALD L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

VOGEL,CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WHITE,CHARLES F
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOLFF,STEVEN N
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
WOODCOCK,THOMAS M
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
WOODCOCK,THOMAS M
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION

L Jun-06-84

AMENDMENT	84-27	DRS	831531
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- (a) CKLST
PT9acd /003-071-023
DP3-71 SUBM 2/21/84; CV SUBM 10/7/82
BITRAN,JACOB
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (b) CKLST
PT9acd /003-071-025
DP3-71 SUBM 2/21/84; CV SUBM 9/10/82
BROUN,GORONWY O
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (c) CV,CKLST
PT9acd /003-071-024
DP3-71 SUBM 2/21/84
STONE,LAWRENCE A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (d) CV,CKLST
PT9acd /003-071-022
DP3-71 SUBM 2/21/84
VOYCE,GARY F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
- (e) CV,CKLST,PROTO,INVES AGR
PT9b /003-074-006
ADDL STUDY BY DR GAMS; CV SUBM
1/4/83; PROT(3-74)SUBM 2/21/84

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 37

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
L Jun-14-84		AMENDMENT IN REFERENCE TO DR NEIDHART'S (#56) BREAST CA STUDY (3-43-1)	84-28	DJF	831543		
		(a) CASE REPORT FORM GLOSSARY OF ABBREV'Ns/CODES(FOR CRFs) PREPARED BY OSU CA CTR					
L Jun-15-84		AMENDMENT	84-29	DRS	831545		
		(a) CKLST PT9a /003-071-014 CV SUBM 7/29/83; DP3-71 SUBM 2/21/84; QAZI CO-INV W/ BENNETT QAZI, RAMAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
L Jun-19-84		AMENDMENT	84-30	DRS	831561		
		(a) CKLST PT9acd /003-071-028 DP3-71 SUBM 2/21/84; CV(& ASSOCs) SUBM 1/4/83, 6/6/84 GAMS, RICHARD A LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		(b) CKLST PT9acd /003-071-029 DP3-71 SUBM 2/21/84; CV(& ASSOCs) SUBM 6/24/83 WIERNIK, PETER H LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		(c) CV(& ASSOCs), CKLST PT9acd /003-071-026 (3-71) SUBM 2/21/84 HEIM, WILLIAM J LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		(d) CV, CKLST PT9acd /003-071-027 (3-71) SUBM 2/21/84 WACHI, DENNIS H LYMPHOMA; vs m-BACOD m-BNCOD COMBO					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 38

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(e) CKLST
PT9acd /003-072-004
DP3-72 SUBM 12/13/83; CV(& ASSOCs) SUBM 10/10/83
ARLIN,ZALMEN A
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
(f) CV(& ASSOCs),CKLST
PT9acd /003-074-007
DP3-74 SUBM 2/21/84
ABRAMSON,NEIL
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
(g) CV,CKLST
PT9acd /003-074-006
DP3-74 SUBM 2/21/84
VILLA,LUIS
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
(h) CKLST
PT9acd /003-074-008
DP3-74 SUBM 2/21/84; CV(&ASSOCs) SUBM 6/24/83
WIERNIK,PETER H
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Jun-22-84 AMENDMENT 84-31 DRS 831566

(a) CV,CKLST
PT9a /003-074-009
DP3-74 SUBM 2/21/84
HICKS,WILLIAM J
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Jul-02-84 AMENDMENT 84-32 DRS 831667

(a) CKLST
PT9a /003-071-030
PROT 3-71 SUBM 2/21/84; CV(& ASSOCs) SUBM 7/13/82,
2/3/83
SILVER,RICHARD T
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
(b) CV,CKLST
PT9b /003-043-001
ROACH REPL NEIDHART(#56) AS PRIN INV IN DP 3-43
SUBM 8/24/82

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 39

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID	
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		ROACH, RALPH W (c) PROTOCOL QAZI FOLLOWING (BUT NOT PART OF) DP3-48 SUBM 2/14/83 QAZI, RAMAN			/003-000-0	
I Jul-12-84		AMENDMENT		84-33	DRS	831691
		(a) CKLST PT9a PROT 3-71 SUBM 2/21/84; CV SUBM 3/7/83 WHITE, CHARLES F LYMPHOMA; vs m-BACOD m-BNCOD COMBO			/003-071-031	
		(b) CKLST PT9b HESKETH REPL LOPEZ AS PRN INV; DP3-40 SUB 7/13/82; CV-4/30/84 HESKETH, PAUL /LOPEZ CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			/003-040-009	
		(c) CV, CKLST PT9b PROT 3-48 SUBM 2/14/83, AMENDED 2/28/84 PORTLOCK, CAROL S CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			/003-048-029	
I Jul-13-84		AMENDMENT		84-34	DRS	831692
		(a) CV # /PT 9 CVs FOR 3 ASSTS UNDER DR GRACE (#63; 3-40-3 -SUBM 7/13/82)				
I Jul-20-84		AMENDMENT		84-35	DRS	831702
		(a) CV # /PT 9 CVs FOR 5 ASSTS TO TRUMP (#128; 3-48-23); 3-48 SUBM 2/14/83				
I Jul-23-84		AMENDMENT		84-36	DJF	831711
		DER FROM DR DAO'S TRIAL (3-40-16) -MULTI-CTR BR CA PROT 3-40				
		(a) DRUG EXPER RPT # /PT 10 PT #3018 (AGE:30yrs) AMENORRHEA, HOT FLASHES				

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 40

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Jul-26-84		AMENDMENT	84-37	DJF	831705
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(a) CKLST
PT9a /003-071-033
PROT 3-71 SUBM 2/21/84; ARMENTROUT'S CV SUBM
9/10/82
ARMENTROUT, STEVEN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
(b) CV,CKLST
PT9a /003-071-032
PROT 3-71 SUBM 2/21/84;
JAFFREY, IRA S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
(c) CV-ASSOC(s)
PT9c /003-071-028
11 ASSOCs TO GAMS (PROT SUBM 2/21/84)

L Jul-27-84	L Jul-13-84	CORRESPONDENCE	DJF	831742
		7/13/84 COVER LTR SHOULD HAVE READ 16,332 & NOT 17,560		

L Jul-30-84		AMENDMENT	84-38	DJF	831740
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(a) CV,CKLST
PT9 /003-074-010
DP3-74 SUBM 2/21/84
WEINTRAUB, LEWIS R
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Aug-06-84		AMENDMENT	84-39	DJF	831756
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(a) CKLST
PT9a /003-074-012
DP3-74 SUBM 2/21/84; CV(& ASSOCs) SUBM 9/3/82
DOTY, GORDON L
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
(b) CV,CKLST
PT9b /003-071-034
DP3-71 SUBM 2/21/84
DOSIK, MICHAEL H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 41

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-07-84		AMENDMENT	84-40	DJF	831763
	(a)	CKLST PT9a DESSER (CV-10/7/82) REPLACES BITRAN AS PR INV FOR 3-71-23 BITRAN, JACOB LYMPHOMA; vs m-BACOD m-BNCOD COMBO DESSER, R K /BITRAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
	(b)	CV-ASSOC(s) # /PT 9b 4 ASSOCs OF DR H GOLOMB FOR 2 BR CA STUDIES -3-40-21, 3-48-21			
L Aug-14-84		AMENDMENT	84-41	DJF	831774
	(a)	CV, CKLST, PROTO PT9,10 UPDATED CV MOORE, JOSEPH O CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
L Aug-15-84		MEETING REQUEST MTG SEPT 24-26: ACUTE LEUKEMIA & NON-HODGKIN'S LYMPH	84-42	DJF	831777
L Aug-16-84		AMENDMENT	84-43	DJF	831812
	(a)	CKLST PT9a 3-74 SUBM 2/21/84; CV(& 13 ASSOCs) SUBM 1/4/83, 6/6, 7/26/84 GAMS, RICHARD A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
	(b)	CV-ASSOC(s) PT9b FOR 2 ASSTS TO DR BRODOVSKY (#109 -3/7/83) IN STUDY 3-48-8			
	(c)	CV-ASSOC(s) PT9b 1 ASST TO DR HOLROYDE (#134 -4/16/84) IN STUDY 3-71-13			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 42

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(d) CV-ASSOC(s) PT9c	/003-048-007		
		(d) CV-ASSOC(s) PT9c	/003-071-031		
		(e) CV-ASSOC(s) PT9d FOR 8 ASSTS	/003-048-023		
L Aug-23-84		AMENDMENT	84-44	DJF	831825
		(a) DEAR INVESTIGATOR LETTER # /PT 7 TO ALL ACTIVE INVs: AMENORRHEA IN PTS BEING TREATED W/ MITOX			
L Aug-24-84		AMENDMENT	84-45	DJF	831829
		(a) ALL INVSTGTRS (EXCEPT HEIM) WILL FOLLOW 3-74 SUBM 2/21/84			
		(b) CKLST PT9b /003-074-016 DP3-74 SUBM 2/21/84; CV(& ASSOCs) SUBM 5/22/84, 8/30/83 GABRIEL, DON A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(c) CKLST PT9a /003-074-017 DP3-74 SUBM 2/21/84; CV(& ASSOCs) SUBM 7/13/82, 2/3/83 SILVER, RICHARD T ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(d) CV(& ASSOCs), CKLST PT9c /003-074-015 DP3-74 SUBM 2/21/84 DOSIK, HARVEY ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(e) CV(& ASSOCs), CKLST PT9c /003-074-014 DP3-74 SUBM 2/21/84 KLOSS, ROBERT A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 43

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(f) CV(& ASSOCs),CKLST PT9c /003-074-013 DP 3-74 SUBM 2/21/84 ROBINSON, WILLIAM ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(g) CV-ASSOC(s) PT9d /003-071-026 FOR 1 ASST TO DR HEIM (#150 - 6/19/84) IN STUDY 3-71-26			
L Aug-30-84		AMENDMENT	84-46	DJF	831835
		(a) CV-ASSOC(s) # /PT 9 1 ASST TO DR WHITE(#116 - 8/17/83); PROT 3-48 SUBM 2/14/83			
		(b) DRUG EXPER RPT # /PT 10 STUDY 3-48-8 (PT: EP #4102): HYPOTENSION			
L Sep-05-84		AMENDMENT	84-47	DJF	831852
		(a) CV(& ASSOCs),CKLST PT9a /003-074-018 DP 3-74 SUBM 2/21/84; CV FOR 4 ASSOCs SCHADE, STANLEY G ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		(b) CV-ASSOC(s) # /PT 9b 1 ASST TO TRUMP(#128,3-48-23,3/27/84); DP3-48 SUBM 2/14/83			
L Sep-06-84		AMENDMENT	84-48	DJF	831853
		(a) CKLST PT9a /003-069-002 DP 3-69 SUBM 8/14/84; CV(& ASSOCs) SUBM 5/22/84 & 8/30/83 BERNARD, STEPHEN A CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
		(b) CV-ASSOC(s) PT9b /003-071-014 BRENNAN, OLSON, ROWE			
		(c) CV-ASSOC(s) PT9c /003-074-007 JADEJA, MAHAJAN			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 44

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
		16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT					
L Sep-12-84		AMENDMENT	84-49	DJF			831861
	(a)	CV(& ASSOCs),CKLST PT9 /003-074-019 DP3-74 SUBM 2/21/84 KARP, DANIEL D ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)					
L Sep-19-84		AMENDMENT	84-51	DJF			831878
	(a)	CKLST PT9a /003-071-035 (3-71-35); CV(& ASSOC) SUBM 1/20/84; DP3-71 SUBM 2/21/84 GEORGE, SEBASTIAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
	(b)	CV-ASSOC(s) # /PT 9b 2 ASSOCs OF DR BITRAN(#87,3-40-23-10/7/82);3-40 SUBM 7/13/82					
	(c)	CV-ASSOC(s) # /PT 9c 7 ASSOCs OF PORTLOCK(#156,3-48-29-7/12/84);3-48 SUBM 2/14/83					
	(d)	DRUG EXPER RPT # /PT 10 PT#1006,3-74-2: DEATH -3hrs AFTER MITO + Ara-C ADMINISTERED					
L Sep-20-84		AMENDMENT	84-52	DJF			831881
	(a)	CV-ASSOC(s) # /PT 9 4 ASSOCs TO TRUMP(#128,3-48-23 3/27/84); DP3-48 SUBM 2/14/83					
L Sep-26-84		AMENDMENT	84-53	DJF			850125
	(a)	CKLST,CV-ASSOC(s) PT9a,b /003-040-021 REPL GOLOMB(#79) AS PR INV IN 3-40 SUBM 7/13/82,AMND 1/10/83 BITRAN,JACOB /GOLOMB CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS GOLOMB,HARVEY M CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 45

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ID
------------------------	-------------------	-------------	--------------------------	---------	------	-------------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(b) CKLST,CV-ASSOC(s)
PT9a,b /003-048-010
BITRAN REPL GOLOMB AS PR INV IN 3-48 SUBM 2/14/83,
A 2/28/84
BITRAN,JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BITRAN,JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
GOLOMB,HARVEY M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
(c) CV-ASSOC(s)
PT9b /003-046-007
3-46 SUBM 12/8/82, AMND 6/21/83; BITRAN'S CV SUBM
10/7/82
(d) CV-ASSOC(s)
PT9c /003-071-034
FOR 12 ASSTs TO DR M DOSIK(#159-8/16/84); 3-71
SUBM 2/21/84
(e) PROTOCOL AMENDMENT
PT10a /003-065-000
A#2 -PROT ORIG SUBM 7/29/83, AMND 8/26/83
(f) PROTOCOL AMENDMENT
PT10b /003-074-000
A#1 -PROT SUBM 2/21/84

L Oct-04-84

AMENDMENT 84-54 DJF 831938

(a) CV(& ASSOCs),CKLST
PT9a /003-074-020
3-74 SUBM 2/21/84, AMENDED 9/26/84
WEAVER,ZEBULON III
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

L Oct-17-84

AMENDMENT 84-55 DJF 831935

(a) CV-ASSOC(s)
PT9 /003-071-001
1 ASST TO CASE (#98,3-71-1 SUBM 2/21/84)

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 46

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Oct-19-84		AMENDMENT	84-56	DJF	831939
		(a) CV-ASSOC(s) # /PT 9 4 ASSTS TO ARLIN (#85,3-44-13,10/1/82); 3-44 SUBM 9/10/82			
L Oct-24-84		AMENDMENT	84-58	DJF	831942
		(a) CKLST & PROTOCOL PT9 /003-074-021 CV SUBM 9/10/82 ARMENTROUT, STEVEN ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Oct-24-84		CORRESPONDENCE	84-57	DJF	831941
		COPY OF 9/26 MINUTES: EVAL'N OF MITO IN PTS W/ LEUK/LYMPHOMA			
L Oct-29-84		AMENDMENT	84-59	DJF	831962
		(a) CKLST & PROTOCOL PT9,10 /003-000-000 CV SUBM 12/3/82 BERNHARDT, BERNARD			
L Nov-05-84		AMENDMENT	84-60	DJF	832033
		(a) CV-ASSOC(s) PT9 /003-046-002 7 ASSTS TO PETERSON (#94-12/8/82); PROT SUBM 12/8/82			
L Nov-07-84		AMENDMENT	84-61	DJF	832036
		(a) CV-ASSOC(s) PT9a /003-071-013 2 ASSTS TO HOLROYDE (#134-4/16/84); DP3-71 SUBM 2/21/84			
		(b) CV-ASSOC(s) PT9b /003-000-000 PHILLIPS ASST'g BERNHARDT IN PROT SUBM 10/29/84, 1PT-COMPASSN			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 47

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Nov-09-84	L Oct-24-84	CORRESPONDENCE	84-62	DJF	832038
		(a) PUBLISHED RPTS SWOG PAPER (CANCER'79): ADRIAMYCIN'S CONTRIBUTION DIFF LYMPH			
L Nov-13-84		AMENDMENT	84-63	DJF	832040
		(a) CKLST PT9 /003-069-003 DP3-69 SUBM 8/14/84; CV(& ASSOCs) SUBM 4/9/84, 7/13/82 SARG, MICHAEL J CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
L Nov-14-84		AMENDMENT	84-64	DJF	832042
		(a) CV-ASSOC(s) PT9a /003-048-020 ASST TO BERNARD (#117-2/1/84); DP3-48 SUBM 2/14/83, A-2/28/84			
		(b) CV-ASSOC(s) PT9b /003-074-015 2 ASSTS TO DOSIK (#163-8/24/84); DP3-74 SUBM 2/21/84, A9/26/84			
L Nov-27-84		AMENDMENT	84-65	DJF	832067
		(a) PROTOCOL AMENDMENT PT10 /003-046-000 AMND MT 2 (DP3-46 ORIG SUBM 12/8/82, FIRST AMND- 6/21/83)			
L Nov-30-84		AMENDMENT	84-67	DJF	832069
		(a) CV, CKLST PT9 /003-000-000 SPAULDING FOLLOWING (BUT NOT PART OF) DP3-40 SUBM 7/13/82 SPAULDING, MONICA B			
L Dec-05-84		AMENDMENT	84-68	DJF	832103
		(a) CV-ASSOC(s) PT9 /003-071-031 ASST TO WHITE (#116, 7/12/84); DP3-71 SUBM 2/21/84			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 48

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Dec-20-84 AMENDMENT 84-69 GRP F 832144
IN SUPPORT OF PRESERV EFFICACY - VIALS AS MULT-DOSE
CONTAINER

- (a) PRESERVATIVE EFFICACY # /PT 5
AT 30 MINS; 1,7,14,21,28 DAYS (EXHIBIT #1)
- (b) PRESERVATIVE EFFICACY # /PT 5
AT 6,24,48 HRS & 7,14,21,28 DAYS (EXHIBIT #2)
- (c) ANALYSES # /PT 5
MULT-USE EVAL'N: REPEATED EXTRACTIONS FROM A
SINGLE VIAL 30d
- (d) MONOGRAPH # 15530 /PT 5
GENERAL MTD: ANTIMICROBIAL PRESERVATIVES
EFFECTIVENESS

L Jan-02-85 AMENDMENT 85-1 DJF 832126

- (a) DRUG EXPER RPT
PT10 /003-074-007
PT#2019 DEATH: FIBRILLATION ATRIAL

L Jan-18-85 AMENDMENT 85-2 DJF 850033

- (a) CKLST, PROT
PT9a,10a /003-076-001
CV SUBM 10/4/84
WEAVER,ZEBULON III
CA-SOLID; COMPASSIONATE
- (b) CV,CKLST,PROTO
PT9b,10b /003-077-001
COOPER,MILES R
LEUKEMIA; COMPASSIONATE

F Jan-22-85 L Oct-24-84 CORRESPONDENCE DJF 850274
IF MITO ADDS TO RESULTS OF H-D CYTARAB (ANLL)
EFFICACY SHOWN

- (a) EFFICACY(NOD LYMPH): IMPROVE QUALITY OF
LIFE; SURVIV DATA REQ

L Feb-19-85 AMENDMENT 85-3 DJF 850120

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 49

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(a) CKLST
PT9a /003-000-000
DP3-65 SUBM 7/29/83, AMENDED 8/26/83, 9/26/84. CV
SUB 2/14/83
HOLLAND, JAMES
(b) CV, CKLST
PT9b /003-076-002
DP3-76 SUBM 1/18/85
GRILLO, JAMES
CA-SOLID; COMPASSIONATE
(c) PROTOCOL AMENDMENT
PT10 /003-075-001
A#1: PTS OVER 70yrs WILL BE ADMITTED; DP3-75 SUBM
2/22/84

L Feb-26-85

AMENDMENT	85-4	DJF	850142
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(a) CV-ASSOC(s)
PT9 /003-071-015
ASST TO SHAW (#138 -5/4/84); DP3-71 SUBM 2/21/84
(b) DRUG EXPERIENCE RPT # /PT 10
(U.K. STUDY 3-563-1, PT# 1/G.N.) INTESTINAL
PERFORATION

L Mar-01-85

AMENDMENT	85-6	DJF	850189
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(a) CV, CKLST
PT9a /003-076-003
PROT SUBM 1/18/85
LOWENBRAUN, STANLEY
CA-SOLID; COMPASSIONATE
(b) CV(& ASSOCs), CKLST
PT9b /003-076-004
PROT SUBM 1/18/85
SCHER, NANCY
CA-SOLID; COMPASSIONATE
(c) CKLST
PT10c /003-076-005
PROT SUBM 1/18/85; CV SUBM 7/26/84 UNDER PROT
3-71-32
JAFFREY, IRA S
CA-SOLID; COMPASSIONATE

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 50

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(d) CKLST PT10d /003-076-006 PROT SUBM 1/18/85; CV SUBM 3/27/84 UNDER PROT 3-48-5 DENEFRIJO, JOHN M CA-SOLID; COMPASSIONATE			
		(e) DR Z WEAVER(#166) WILL BE TREATING AN ADDL PATIENT			/003-076-0
		(f) DR COOPER(#170) WILL BE TREATING AN ADDL PATIENT			/003-077-0
L Mar-08-85		AMENDMENT	85-8	DJF	850179
		(a) DRUG EXPERIENCE RPT # /PT 10 (CANADA) EXTRAVASATION; SWELLING, BLISTERING, WEAKNESS -HAND			
L Mar-15-85		AMENDMENT	85-8	DJF	850214
		(a) CV(& ASSOCs),CKLST PT9 /003-077-002 PROT SUBM 1/18/85 McFARLAND, JAMES A LEUKEMIA; COMPASSIONATE			
L Mar-25-85		AMENDMENT	85-9	DJF	850239
		(a) CV(& ASSOCs),CKLST PT9a /003-076-007 PROT SUBM 1/18/85 HORVATH, WILLIAM L CA-SOLID; COMPASSIONATE			
		(b) CV-ASSOC(s) PT9b /003-074-015 2 ASSTS TO DOSIK; PROT SUBM 2/21/84			
L Apr-10-85		AMENDMENT	85-10	DJF	850310
		(a) CV,CKLST PT9 /003-076-008 PROT SUBM 1/18/85 STRUM, STEPHEN B CA-SOLID; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 51

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			

L Apr-15-85	AMENDMENT	85-11	DJF	850313
	(a) CKLST, PROT, CV-ASSOC(s) PT9 /003-074-022 PROT SUBM 2/21/84, AMND 9/26/84; CV SUBM 8/14/84 MOORE, JOSEPH O ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
	(b) DRUG EXPERIENCE RPT PT10 /003-070-001 PT #25: TISSUE NECROSIS			
L Apr-23-85	AMENDMENT	85-12	DJF	850348
	(a) CV(& ASSOCs), CKLST PT9 /003-076-009 PROT SUBM 1/18/85 GOTTLIEB, ROBERT J CA-SOLID; COMPASSIONATE			
	(b) /003-071-0 BERKOWITZ (CV SUBM 8/24/84) ADDED AS ASST INVESTIGATOR			
L May-10-85	AMENDMENT	85-13	DJF	850459
	(a) CV, CKLST PT9 /003-076-010 PROT SUBM 1/18/85 ROBERTS, JOHN CA-SOLID; COMPASSIONATE			
	(b) CV(& ASSOCs), CKLST, PROT PT9, 10 /003-079-001 SRIDHAR, KASI CA-HEAD & NECK			
	(c) CV(& ASSOCs), CKLST, PROT PT9, 10 /003-080-001 KELSEN, DAVID CA-STOMACH			
L May-14-85	AMENDMENT	85-14	DJF	850468

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 52

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(a) CV,CKLST PT9a /003-076-011 PROT SUBM 1/18/85 KOO, VICTOR S CA-SOLID; COMPASSIONATE			
		(b) CV(& ASSOCs),CKLST PT9b /003-077-004 PROT SUBM 1/18/85 FORTE, FRANCIS A LEUKEMIA; COMPASSIONATE			
L May-15-85		AMENDMENT	85-15	DJF	850469
		(a) CV(& ASSOCs),CKLST PT9 /003-077-003 PROT SUBM 1/18/85 ALBALA, MAURICE LEUKEMIA; COMPASSIONATE			
L May-21-85		AMENDMENT	85-16	DJF	850473
		(a) CKLST PT9 /003-076-012 PROT SUBM 1/18/85; CV(& ASSOCs) SUBM 5/14/85 FORTE, FRANCIS A CA-SOLID; COMPASSIONATE			
L May-24-85		AMENDMENT	85-17	DJF	850440
		(a) CKLST # /PT 9 CURRENTLY ACTIVE INVESTIGATORS (AS OF 4/15/85) (b) PROGRESS RPT # /PT 10 ABRAMSON, NEIL ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) ALBERTS, DAVID S CA-OV, COLON; DOSE RANGING PK OF IP ADMINISTRATION ALLEGRA/WOODCOCK CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS AMARE LEUKEMIA			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

ARLIN, ZALMEN A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

ARLIN, ZALMEN A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

ARLIN, ZALMEN A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

ARLIN, ZALMEN A
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION

ARLIN, ZALMEN A
LEUKEMIA

ARLIN, ZALMEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ARMENTROUT, STEVEN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
ARMENTROUT, STEVEN
LEUKEMIA

ARMENTROUT, STEVEN
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
BENIGNO, BENEDICT R

CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

BENNETT, J/QAZI, RAMAN
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

BENNETT, J/QAZI, RAMAN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

BERNARD, STEPHEN A
CA-LUNG

WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA
BERNARD, STEPHEN A

CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BERNARD, STEPHEN A

CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

BERNHARDT, BERNARD
BITRAN, JACOB /GOLOMB
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLOCK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
BLUMING, AVRUM Z
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BRODORSKY
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
BROUN, GORONWY O
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
BROUN, GORONWY O
LEUKEMIA

BYRNE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
CASE, DELVYN C
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
CASE, DELVYN C
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
CASE, DELVYN C
LYMPHOMA
NON-HODGKIN'S
CASSILETH
LEUKEMIA

CHLEBOWSKI
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
CHLEBOWSKI
HEPATOMA

COHEN, RICHARD J
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
CONRAD, MARCEL E
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ----- Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

CONRAD, MARCEL E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
COOPER, MILES R
LEUKEMIA; COMPASSIONATE

COSTANZI, JOHN J
LYMPHOMA
NON-HODGKIN'S
DAO
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DENEFRIOS, JOHN M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DENEFRIOS, JOHN M
CA-SOLID; COMPASSIONATE

DESAI
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DESSER, R K
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOROSHOW
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
DOSIK, HARVEY
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
DOSIK, MICHAEL H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOTY, GORDON L
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
DOTY, GORDON L
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
DOTY, GORDON L
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
DRESDNER, DAVID M
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		DRESDNER, DAVID M LYMPHOMA; vs m-BACOD m-BNCOD COMBO DUGAN CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS ERSLEV, ALLAN J LEUKEMIA			
		ERSLEV, ALLAN J LYMPHOMA NON-HODGKIN'S FASS, LEROY LYMPHOMA; vs m-BACOD m-BNCOD COMBO GABRIEL, DON A LYMPHOMA; vs m-BACOD m-BNCOD COMBO GABRIEL, DON A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) GAMS, RICHARD A LYMPHOMA NON-HODGKIN'S GAMS, RICHARD A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) GAMS, RICHARD A LYMPHOMA; vs m-BACOD m-BNCOD COMBO GAMS, RICHARD A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU GAMS, RICHARD A LEUKEMIA			
		GEORGE, SEBASTIAN CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU GEORGE, SEBASTIAN LYMPHOMA; vs m-BACOD m-BNCOD COMBO GOLOMB, HARVEY M LYMPHOMA NON-HODGKIN'S			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		GOODMAN, GARY E LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		GRACE, WILLIAM R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		GRILLO, JAMES CA-SOLID; COMPASSIONATE			
		GROPPE, CARL W ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO w CYTOSAR (ARA-C)(CYTARABINE)			
		HEIM, WILLIAM J LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		HENDERSON, I CRAIG CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
		HESKETH, PAUL CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		HICKS, WILLIAM J ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO w CYTOSAR (ARA-C)(CYTARABINE)			
		HOLLAND, JAMES LEUKEMIA			
		HOLLAND, JAMES F HOLLAND, JAMES F ALL COMBINED w/ VINCERISTINE & DEXAMETHASONE			
		HOLLAND, JAMES F LYMPHOMA COMBINED w/ VINCERISTINE & DEXAMETHASONE			
		HOLROYDE, CRISTPHER P LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		HORVATH, WILLIAM L CA-SOLID; COMPASSIONATE			
		JAFFREY, IRA S CA-SOLID; COMPASSIONATE			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	ReSp	Event ----- Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

JAFFREY, IRA S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
JONES, ROY
CA-BREAST; DOSE RANGING
ESCALATING DOSE -CARDIAC MEASUREMENTS
JONES, STEPHEN E
LYMPHOMA
NON-HODGKIN'S
KARP, DANIEL D
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
KENNEDY, PETER S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
KLOSS, ROBERT A
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
KRAKOFF, I H
KRAKOFF, I H
CA-BREAST
COMB w/ CYCLOPHOS, 5-FU X-OVER TO
ADRIAMYCIN/VINBLASTINE
KREMENTZ, EDWARD T
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
KREMENTZ, EDWARD T
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
LAWSON
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
LEVICK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
LEVINE, JAMES D
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
LOWENBRAUN, STANLEY
CA-SOLID; COMPASSIONATE
MABRY, R JAMES
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
MOORE, JOSEPH O
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		MOORE,JOSEPH O CA-LUNG WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA			
		MOORE,JOSEPH O ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		MOORE,JOSEPH O LEUKEMIA			
		MORGAN,LEE ROY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		MUGGIA,FRANCO CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		MUSS CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		McFARLAND,JAMES A LEUKEMIA; COMPASSIONATE			
		OISHI,NOBORU CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		PETERSEN LYMPHOMA NON-HODGKIN'S			
		PLOTKIN,DAVID CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		PORTLOCK,CAROL S CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		PRESANT,CARY A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		QAZI,RAMAN RIVKIN,SAUL E LYMPHOMA NON-HODGKIN'S			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

ROACH, RALPH W
ROBINSON, WILLIAM
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
ROSS
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SAMUELS, ARTHUR J
SARG, MICHAEL J
CA-LUNG
WITH CIS-PLATINUM IN ADENO CA OR LARGE CELL CA
SARTIANO, GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SARTIANO, GEORGE P
LEUKEMIA

SCHADE, STANLEY G
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
SCHER, NANCY
CA-SOLID; COMPASSIONATE

SCHWARTZ, I ROBERT
LEUKEMIA

SCOTT, ROBERT B
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
SEBASTIAN, GEORGE
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
SHAW, JOHN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
SILVER, RICHARD T
LYMPHOMA
NON-HODGKIN'S
SILVER, RICHARD T
LEUKEMIA

SILVER, RICHARD T
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
SILVER, RICHARD T
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

SPAULDING,MONICA B
SPICER
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
STEIN,RICHARD S
LYMPHOMA
NON-HODGKIN'S
STEIN,RICHARD S
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
STONE,LAWRENCE A
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
STRU,STEPHEN B
CA-SOLID; COMPASSIONATE

STUART,JOHN J
LYMPHOMA
NON-HODGKIN'S
STUART,JOHN J
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
TRANUM,BILL L
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
TRUMP,DONALD L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
VILLA,LUIS
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)
VOGEL,CHARLES L
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
VOLBERDING
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
VOYCE,GARY F
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WACHI,DENNIS H
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
WEAVER,ZEBULON III
ANLL; vs CERUBIDINE & CYTOSAR (ARA-C)
IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		WEAVER,ZEBULON III CA-SOLID; COMPASSIONATE			
		WEIDEN CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		WEINTRAUB,LEWIS R ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		WHITE CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		WHITE,CHARLES F LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		WHITE,CHARLES F CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		WIERNIK,PETER H LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		WIERNIK,PETER H ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
		WIERNIK,PETER H LEUKEMIA			
		WOLFF,STEVEN N CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		WOLFF,STEVEN N CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU			
		WOLFF,STEVEN N LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		WOODCOCK,THOMAS M CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
		WOODCOCK,THOMAS M LYMPHOMA; vs m-BACOD m-BNCOD COMBO			
		(c) TOXICOLOGY STUDIES # /PT 10 APPENDED CARDIOTOXICITY REPORT			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 63

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L May-29-85		AMENDMENT	85-18	DJF	850512
	(a)	CV(& ASSOCs),CKLST PT9a /003-076-014 COMPASSIONATE PROT (SOLID TUMORS) SUBM 1/18/85 NELSON,ERIC C CA-SOLID; COMPASSIONATE			
	(b)	CV(& ASSOCs),CKLST PT9b /003-077-005 COMPASSIONATE PROT (LEUKEMIA) SUBM 1/18/85			
L May-30-85		AMENDMENT	85-19	DJF	850511
	(a)	CV-ASSOC(s) PT9 /003-074-015 CV FOR DR S ROTHENBERG; PROT SUBM 2/21/84, AMENDED 8/24/84			
L Jun-03-85		AMENDMENT	85-20	DJF	850533
	(a)	CV,CKLST PT9 /003-046-003 MILLER REPLACES JONES AS PRINC INVEST; PROT SUBM 12/8/82 JONES,STEPHEN E LYMPHOMA NON-HODGKIN'S MILLER,THOMAS /JONES LYMPHOMA NON-HODGKIN'S			
L Jun-25-85		AMENDMENT	85-21	DJF	850599
	(a)	CV-ASSOC(s) PT9a /003-048-028 7 ASSOCs; PROT SUBM 2/21/84			
	(b)	CV,CKLST PT9b /003-076-015 COMPASSIONATE PROT SUBM 1/18/85 ARENA,PAUL CA-SOLID; COMPASSIONATE			
	(c)	CV,CKLST PT9b /003-076-017 COMPASSIONATE PROT SUBM 1/18/85			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 64

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

BUDD, THOMAS G
CA-SOLID; COMPASSIONATE

(d) CV(& ASSOCs), CKLST
PT9c /003-077-006
COMPASSIONATE PROT SUBM 1/18/85
SAUNDERS, DARRELL F
LEUKEMIA; COMPASSIONATE

(e) CV(& ASSOCs), CKLST
PT9d /003-044-000
(ONE PT) FOLLOWING MITO TRMT SECT OF LEUK PROT
SUBM 9/10/82
ALGAZY, KENNETH M
LEUKEMIA

L Jun-26-85 AMENDMENT 85-22 DJF 850606

(a) CV(& ASSOCs), CKLST, PROT
PT9,10 /003-079-002
ERVIN, THOMAS
CA-HEAD & NECK

L Jul-08-85 AMENDMENT 85-23 DJF 850659

(a) CV(& ASSOCs), CKLST
PT9 /003-080-002
PROT SUBM 5/10/85
BENEDETTO, PASQUALE
CA-STOMACH

L Jul-31-85 AMENDMENT 85-24 DJF 850700

(a) CV-ASSOC(s)
PT9 /003-079-002
2 ASSOCs TO ERVIN (#187); PROT SUBM 6/26/85

(b) PROTOCOL AMENDMENT
PT10 /003-072-000
A#1: OPTIONAL TESTS; PROT SUBM 12/13/83

(c) PROTOCOL AMENDMENT
PT10 /003-072-000
A#2: MISCELLANEOUS CHANGES; PROT SUBM 12/13/83

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 65

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-02-85		AMENDMENT	85-25	DJF	850769
	(a)	CV(& ASSOCs),CKLST PT9ab /003-072-005 UPDATED CVs (PROT SUBM 12/13/83, AMENDED I&II 7/31/85) CASE,DELVYN C CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
L Aug-06-85		AMENDMENT	85-26	DJF	850753
	(a)	PROTOCOL AMENDMENT PT10a /003-046-010 A #2A: MUGA SCAN OR ECHO ALLOWED (PROT SUBM 12/8/82)			
	(b)	PROTOCOL AMENDMENT PT10b /003-071-030 A #1A: MUGA SCAN OR ECHO ALLOWED (PROT SUBM 2/21/84)			
L Aug-07-85		AMENDMENT	85-27	DJF	850755
	(a)	PROTOCOL AMENDMENT PT10 /003-074-000 A#2: NO CNS LEUK AT BASELINE (PROT SUBM 2/21/84)			
L Aug-12-85		AMENDMENT	85-28	DJF	850791
	(a)	CV,CKLST PT9 /003-076-019 PROT SUBM 1/18/85 SMITH,FREDERICK P CA-SOLID; COMPASSIONATE			
L Aug-16-85		AMENDMENT	85-29	DJF	850803
	(a)	CV,CKLST PT9 /003-076-022 UPDATED CV; PROT SUBM 1/18/85 BERTINO,JOSEPH CA-SOLID; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 66

Lead/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Aug-21-85		AMENDMENT	85- 30	DJF	850811
	(a)	CV(& ASSOCs),CKLST PT9a /003-076-023 PROT SUBM 1/18/85 VERDIRAME, JOSEPH CA-SOLID; COMPASSIONATE			
	(b)	CV-ASSOC(s) PT9b /003-079-001 4 ASSTS TO SRIDHAR (#178); CV & PROT SUBM 5/10/85			
	(c)	CV-ASSOC(s) PT9b /003-080-002 4 ASSTS TO BENEDETTO (#191 CV SUBM 7/8/85); PROT SUBM 5/10/85			
L Sep-03-85		AMENDMENT	85- 31	DJF	850865
	(a)	CKLST PT9a /003-076-020 PROT SUBM 1/18/85; CV(& ASSOCs) SUBM 5/29/85 PAPISH, STEPHEN W CA-SOLID; COMPASSIONATE			
	(b)	CV,CKLST PT9b /003-076-025 PROT SUBM 1/18/85 KUBOTA, THOMAS T CA-SOLID; COMPASSIONATE			
L Sep-05-85		AMENDMENT	85- 32	DJF	850866
	(a)	CV,CKLST PT9 /003-077-007 UPDATED CV; PROT SUBM 1/18/85 STUART, JOHN LEUKEMIA; COMPASSIONATE			
L Sep-06-85		AMENDMENT	85- 33	DJF	850760
	(a)	DRUG EXPERIENCE RPT PT10 /003-070-001 (FOLL UP TO 4/15/85 RPT) PT#25: TISSUE NECROSIS			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 67

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT					
(b) DRUG EXPERIENCE RPT # /PT 10 (AUSTRALIA - COMPASSIONATE PT) TISSUE NECROSIS					
L Sep-23-85		AMENDMENT	85-34	DJF	850840
(a) CV(& ASSOCs),CKLST PT9a /003-077-010 PROT SUBM 1/10/85					
(b) DRUG EXPERIENCE RPT # /PT 10 (WG) DEATH: OVERDOSE EFFECT; APLASIA BONE MARROW KOWAL-VERN,ARETA LEUKEMIA; COMPASSIONATE					
L Sep-25-85		AMENDMENT	85-35	DJF	850965
(a) CV,CKLST PT9 /003-076-018 PROT SUBM 1/18/85 SCHELL,FRANK CJ CA-SOLID; COMPASSIONATE					
(b) PROTOCOL PT10a /003-075-000 FINAL COPY OF PROTOCOL, ORIGINALLY SUBM 2/22/84					
(c) PROTOCOL AMENDMENT PT10b /003-075-000 A#2: DOSAGE ADJUSTMT; PROT (RE)SUBM 9/25/85, A#1 - 2/19/85					
L Oct-11-85		AMENDMENT	85-36	DJF	850967
(a) CV,CKLST PT9 /003-077-009 PROT SUBM 1/18/85 DENHAM,CLAUDE A LEUKEMIA; COMPASSIONATE					
L Oct-16-85		AMENDMENT	85-37	DJF	850974
(a) CV,CKLST PT9a /003-077-011 UPDATED CV; PROT SUBM 1/18/85 ARLIN, ZALMEN A LEUKEMIA; COMPASSIONATE					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 68

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		(b) CV-ASSOC(s) PT9b /003-077-007 FOR 9 ASST INVESTIGATORS; PROT SUBM 1/18/85			
L Oct-23-85		AMENDMENT	85-39	DJF	851018
		(a) SUMMARY, PRECLINICAL # /PT 6 ACUTE INTRAVESICULAR & INTRAPERITONEAL STUDIES IN DOGS			
		(b) CV,CKLST,PROTO PT9 /003-082-001 DP3-78 REV'd/RESUBM'd 1/13/86 AS DP3-82; ALBERTS' CV 2/22/84 ALBERTS, DAVID S CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82			
L Oct-23-85		AMENDMENT	85-38	DJF	851007
		(a) CV-ASSOC(s) PT9 /003-037-001 FOR LOCKER, TREATING PT #35 WHO MOVED FROM UCLA TO ILLINOIS			
L Oct-25-85		AMENDMENT	85-40	DJF	851035
		(a) INVESTIGATOR BROCHURE # /PT 7 ISSUE DATE 10/15/85			
L Oct-30-85		AMENDMENT	85-41	DJF	850969
		(a) CV,CKLST PT9a /003-076-033 PROT SUBM 1/18/85 DEUR, CHARLES J CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-026 UPDATED CV; PROT SUBM 1/18/85 MUGGIA, FANCO CA-SOLID; COMPASSIONATE			
		(c) CV,CKLST PT9c /003-076-024 PROT SUBM 1/18/85			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 69

Lead/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

WALLACE, JAMES H
CA-SOLID; COMPASSIONATE

(d) CV,CKLST
PT9d /003-077-012
PROT SUBM 1/18/85
DeGREEN, PETER
LEUKEMIA; COMPASSIONATE

(e) CV(& ASSOCs),CKLST
PT9e /003-077-013
PROT SUBM 1/18/85
SCHECTER, GERALDINE
LEUKEMIA; COMPASSIONATE

(f) DRUG EXPERIENCE RPT
PT10 /003-044-002
PT # 5035 DEATH: JAUNDICE

[Nov-04-85

AMENDMENT	85-42	DJF	851093
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(a) CV(& ASSOCs),CKLST
PT9 /003-046-006
WHEELER REPLACES GAMS AS PRINC INVEST; PROT SUBM
12/8/82
GAMS, RICHARD A
LYMPHOMA
NON-HODGKIN'S
WHEELER, RICHARD
LYMPHOMA
NON-HODGKIN'S

(b) CV(& ASSOCs),CKLST
PT9 /003-044-008
WHEELER REPLACES GAMS AS PRINC INVEST; PROT SUBM
9/10/82
GAMS, RICHARD A
LEUKEMIA

WHEELER, RICHARD
LEUKEMIA

[Nov-11-85

AMENDMENT	85-43	DJF	851101
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(a) CV(& ASSOCs),CKLST
PT9 /003-076-032
COMPASSIONATE PROT SUBM 1/18/85

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 70

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due	ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT				
		FIELDER,KATHLEEN CA-SOLID; COMPASSIONATE				
L Nov-14-85		AMENDMENT	85-44	DJF	851094	
(a)	CKLST PT9a	/003-076-037 COMPASSIONATE PROT SUBM 1/18/85 ROSS, MICHAEL CA-SOLID; COMPASSIONATE				
(b)	CKLST PT9b	/003-048-013 WHEELER (CV SUBM 11/4/85) REPLACES GAMS; PROT SUBM 2/14/83 GAMS, RICHARD A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU WHEELER, RICHARD CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU				
(c)	CKLST PT9b	/003-071-028 WHEELER (CV SUBM 11/4/85) REPLACES GAMS; PROT SUBM 2/21/84 GAMS, RICHARD A LYMPHOMA; vs m-BACOD m-BNCOD COMBO WHEELER, RICHARD LYMPHOMA; vs m-BACOD m-BNCOD COMBO				
(d)	CKLST PT9b	/003-074-011 WHEELER (CV & ASSOCs' SUBM 11/4/85) REPL GAMS; PROT 2/21/84 GAMS, RICHARD A ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) WHEELER, RICHARD ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				

REGULATORY AFFAIRS
LEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 71

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOKANTRONE CL 232,315 ANTICANCER AGENT			
L Nov-18-85		AMENDMENT	85-45	DJF	851104
	(a)	CV(& ASSOCs),CKLST PT9a /003-076-034 COMPASSIONATE PROT SUBM 1/18/85 DANNEMAN, Wm G CA-SOLID; COMPASSIONATE			
	(b)	CV(& ASSOCs),CKLST PT9b /003-077-014 COMPASSIONATE PROT SUBM 1/18/85 STRAUSS, JAMES F LEUKEMIA; COMPASSIONATE			
F Nov-18-85		REQUIREMENT FDA REQUIRES LED TO SUBMIT PAST PROGRESS REPORTS		DJF	851136
L Nov-21-85		AMENDMENT	85-46	DJF	851116
	(a)	CKLST PT9 /003-076-035 CV SUBM 7/9/82; ASSOC CVs SUBM 7/9/82, 10/27/83; PROT 1/18/85 LEVICK, STANLEY N CA-SOLID; COMPASSIONATE			
L Nov-26-85	F Nov-18-85	CORRESPONDENCE LED IS INDEED UP TO DATE IN FILING PROGRESS REPORTS	85-47	DJF	851137
L Dec-09-85		AMENDMENT	85-49	DJF	851176
	(a)	CV,CKLST PT9 /003-076-028 CV SUBM 3/11/85; PROT SUBM 1/11/85 McFARLAND, JAMES A CA-SOLID; COMPASSIONATE			
	(b)	CV,CKLST PT9 /003-076-046 CV SUBM 4/25/84; PROT SUBM 1/11/85			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 72

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		BENNETT,JOHN M CA-SOLID; COMPASSIONATE			
L Dec-12-85		AMENDMENT	85-50	DJF	851192
	(a)	CV,CKLST PT9 /003-076-044 PROT SUBM 1/11/85 BALA,AYER CA-SOLID; COMPASSIONATE			
	(b)	CV(& ASSOCs),CKLST PT9 /003-076-045 PROT SUBM 1/11/85 PANDYA,KISHAN J CA-SOLID; COMPASSIONATE			
L Dec-16-85		AMENDMENT	85-51	DJF	851214
	(a)	CV,CKLST PT9a /003-077-018 PROT SUBM 1/11/85 (UPDATED CV) SILVER,RICHARD T LEUKEMIA; COMPASSIONATE			
	(b)	CV,CKLST PT9b /003-076-051 PROT SUBM 1/11/85 HENDERSON,CHARLES A CA-SOLID; COMPASSIONATE			
L Dec-23-85		AMENDMENT	85-53	DJF	851217
	(a)	CV(& ASSOCs),CKLST PT9 /003-074-025 PROT SUBM 2/21/84 RUBIN,ARNOLD D ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Jan-03-86		AMENDMENT	86-1	DJF	860011
	(a)	CV # /PT 9 CV FOR DR S SALETAN WHO REPLACES DUKART AS LED MONITOR			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 73

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event ID

16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT				
		(b) PROTOCOL AMENDMENT PT10 /003-072-000 A#3: DELETION OF PK ANALYSES; PROT SUBM 12/13/83				
L Jan-13-86		AMENDMENT	86-1	DJF		860547
		(a) PROTOCOL PT10 /003-082-001 PROT REVISED (WAS 3-78) BASED ON TOXICITIES FROM CANADA STUD				
L Jan-15-86		AMENDMENT	86-2	DJF		860548
		(a) CV(& ASSOCs),CKLST PT9 /003-077-015 GRONCY,PAULA LEUKEMIA; COMPASSIONATE				
L Jan-17-86		AMENDMENT	86-3	DJF		860549
		(a) CV(& ASSOCs),CKLST PT9 /003-074-026 PROT SUBM 2/21/84 KATTLOVE,HERMAN ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)				
L Jan-29-86		AMENDMENT	86-4	DJF		860077
		(a) CV,CKLST PT9a /003-076-021 PROT SUBM 1/11/85 PETERSON,JAY T CA-SOLID; COMPASSIONATE				
		(b) CV,CKLST PT9b /003-077-019 PROT SUBM 1/11/85 HANSON,JOHN P LEUKEMIA; COMPASSIONATE				
L Feb-03-86		AMENDMENT	86-5	DJF		860092
		(a) CV,CKLST PT9a /003-076-049 PROT SUBM 1/11/85				

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 74

Led/ Event FCA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		SCHREEDER, MARSHALL T CA-SOLID; COMPASSIONATE			
		(a) CV,CKLST PT9b /003-076-043 PROT SUBM 1/11/85 SCHREEDER, MARSHALL T CA-SOLID; COMPASSIONATE			
L Feb-05-86		AMENDMENT	86-6	DJF	860096
		(a) CKLST PT9 /003-072-006 PROT SUBM 12/3/83; CV(& ASSOCs) SUBM 11/4/85 WHEELER, RICHARD H CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION			
L Feb-05-86		AMENDMENT	86-7	DJF	860095
		(a) CV,CKLST PT9a /003-076-050 PROT SUBM 1/11/85 ALAVI, JANE B CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-052 PROT SUBM 1/11/85 BLOW, ALTON J CA-SOLID; COMPASSIONATE			
L Feb-18-86		AMENDMENT	86-8	DJF	860116
		(a) CV(& ASSOCs),CKLST PT9 /003-074-027 PROT SUBM 2/21/84 BICKERS, JOHN N ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Feb-19-86		AMENDMENT	86-9	DJF	860102
		(a) CV,CKLST PT9a /003-076-054 PROT SUBM 1/11/85			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 75

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		FEINER, ALAN S CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9a /003-076-062 PROT SUBM 1/11/85 FREDRIC, RHETT K CA-SOLID; COMPASSIONATE			
L Feb-25-86		AMENDMENT	86-11	DJF	860148
		(a) CV(& ASSOCs),CKLST PT9 /003-076-048 PROT SUBM 1/1/86 HARRIS, WILLIAM KING, GERALD W CA-SOLID; COMPASSIONATE			
L Feb-25-86		CORRESPONDENCE FDA AUTH'D TO X-REF IND FOR COOPER, STUART&PACIUCCI's FILING	86-10	DJF	860159
L Mar-19-86		AMENDMENT LED PROPOSAL FOR EXPEDITING USE OF MITO ON COMPASSION BASIS	86-12	DJF	860215
L Mar-19-86		AMENDMENT	86-13	DJF	860216
		(a) CKLST PT9a /003-076-036 GRACE'S CV SUBM 7/13/82; PROT SUBM 1/11/85 GRACE, WILLIAM R CA-SOLID; COMPASSIONATE			
		(b) CV,CKLST PT9b /003-076-040 PROT SUBM 1/11/85 ENGELBERG, CHARLES B CA-SOLID; COMPASSIONATE			
		(c) CV(& ASSOCs),CKLST PT9c /003-077-016 PROT SUBM 1/11/85			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 76

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

O'CONNELL, JOSEPH
LEUKEMIA; COMPASSIONATE

L Mar-20-86 AMENDMENT 86-15 DJF 860218

(a) CV, CKLST
PT9a /003-077-024
PROT SUBM 1/11/85
SENECAL, FRANCIS M
LEUKEMIA; COMPASSIONATE

(b) CKLST, CV-ASSOC(s)
PT9b /003-077-026
DESAI'S CV SUBM 11/18/85; PROT SUBM 1/11/85
DESAI, AJIT M
LEUKEMIA; COMPASSIONATE

(c) CV, CKLST
PT9c /003-077-032
PROT SUBM 1/11/85
MEARS, J GREGORY
LEUKEMIA; COMPASSIONATE

L Mar-20-86 AMENDMENT 86-14 DJF 860217

(a) CV(& ASSOCs), CKLST
PT9a /003-076-047
PROT SUBM 1/11/85
GOODWIN, J WENDALL
CA-SOLID; COMPASSIONATE

(b) CV, CKLST
PT9b /003-076-053
PROT SUBM 1/11/85
STALLINGS, LAWRENCE M
CA-SOLID; COMPASSIONATE

(c) CV, CKLST
PT9c /003-076-061
PROT SUBM 1/11/85
McMAHON, RICHARD T
CA-SOLID; COMPASSIONATE

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 77

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Mar-21-86		AMENDMENT	86-16	DJF	860219
	(a)	CV,CKLST PT9 PROT SUBM 1/11/85 McKEOWN, JOHN M CA-SOLID; COMPASSIONATE	/003-076-072		
L Mar-31-86		AMENDMENT	86-17	DJF	860263
	(a)	CV(& ASSOCs),CKLST PT9 PROT SUBM 12/13/83 BENNETT, JOHN M CA-BREAST; SPECIAL-PK INFLUENCE OF HEPATIC FUNCTION	/003-072-007		
	(b)	PROTOCOL AMENDMENT PT10 A#3: ALLOWS FOR CONTINUOUS (UNDRAINED) DWELL TIME	/003-075-001		
L Apr-09-86		AMENDMENT	86-18	DJF	860550
	(a)	CV(& ASSOCs),CKLST,PROT PT9,10 HOLLAND, JAMES F CA-BREAST PHS I&II. COMBINATION OF NOVANTRONE w THIOTEPAN &METHOTREXATE	/003-081-001		
L Apr-10-86		AMENDMENT	86-19	DJF	860339
	(a)	CV(& ASSOCs),CKLST PT9a PROT SUBM 1/11/85 BEARDEN, JAMES D III CA-SOLID; COMPASSIONATE	/003-076-030		
	(b)	CV(& ASSOCs),CKLST PT9b PROT SUBM 1/11/85 NOMANBHoy, YUNUS T CA-SOLID; COMPASSIONATE	/003-076-065		

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 78

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L Apr-15-86		AMENDMENT	86-20	DJF	860341
	(a)	CV,CKLST PT9 /003-076-060 PROT SUBM 1/11/85 HAROLD,SUSAN E CA-SOLID; COMPASSIONATE			
L May-20-86		AMENDMENT	86-21	DJF	860493
	(a)	CV(& ASSOCs),CKLST PT9 /003-074-028 PROT SUBM 2/21/84 STEIN,RICHARD S ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L May-27-86		AMENDMENT	86-22	DJF	860512
	(a)	CV,CKLST PT9 /003-074-029 PROT SUBM 2/21/84 DARA,PARVEZ ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)			
L Jun-06-86		AMENDMENT	86-23	DJF	860551
	(a)	CV PT9a /003-082-001 UPDATED CV FOR ALBERTS & STANISIC (WHO IS NOW ASSOC INVESTR)			
	(b)	CV(& ASSOCs),CKLST PT9b /003-082-002 PROT SUBM 1/13/86 SHARIFI,R /LAMB,D CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82			
L Jun-25-86		AMENDMENT	86-23	DJF	860612
	(a)	CKLST # /PT 9 LIST OF CURRENTLY ACTIVE INVESTIGATORS			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(b) PROGRESS RPT # /PT 10a
ALSO, REFER TO SAFETY UPDATE SUBM'd 2/25/86 TO NDA
19-297

AHR, DAVID
CA-SOLID; COMPASSIONATE

ALAVI, JANE B
CA-SOLID; COMPASSIONATE

ALBALA, MAURICE
LEUKEMIA; COMPASSIONATE

ALI, I
LEUKEMIA; COMPASSIONATE

ALLEGRA/WOODCOCK
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
AMARE
LEUKEMIA

ARENA, PAUL
CA-SOLID; COMPASSIONATE

ARLIN, ZALMEN A
LEUKEMIA; COMPASSIONATE

ARLIN, ZALMEN A
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ARMENTROUT, STEVEN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
ASBURY, ROBERT
CA-SOLID; COMPASSIONATE

BABCOCK, Wm
LEUKEMIA; COMPASSIONATE

BALA, AYER
CA-SOLID; COMPASSIONATE

BEARDEN, JAMES D III
CA-SOLID; COMPASSIONATE

BENEDETTO, PASQUALE
CA-STOMACH

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		BENIGNO, BENEDICT R CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU BENJAMIN, ROBERT CA-SOLID; COMPASSIONATE			
		BENNETT, JOHN M CA-SOLID; COMPASSIONATE			
		BERNARD, STEPHEN A CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		BERNARD, STEPHEN A CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU BERTINO, JOSEPH CA-SOLID; COMPASSIONATE			
		BIRDWELL, ROBERT CA-SOLID; COMPASSIONATE			
		BITRAN, JACOB /GOLOMB CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		BLOCK CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			
		BLOW, ALTON J CA-SOLID; COMPASSIONATE			
		BLUMING, AVRUM Z LYMPHOMA; vs m-BACOD m-BNCOD COMBO BRADY, ALBERT CA-SOLID; COMPASSIONATE			
		BRODORSKY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU BUDD, THOMAS G CA-SOLID; COMPASSIONATE			
		BURTON, GARY LEUKEMIA; COMPASSIONATE			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		CASIMIR, MIRTHA CA-SOLID; COMPASSIONATE			
		CHLEBOWSKI HEPATOMA			
		CHU, ALBERT LEUKEMIA; COMPASSIONATE			
		COLEMAN, MORTON CA-SOLID; COMPASSIONATE			
		CONRAD, MARCEL E CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU CONRAD, MARCEL E LYMPHOMA; vs m-BACOD m-BNCOD COMBO COOPER, MILES R LEUKEMIA; COMPASSIONATE			
		COSTANZI, JOHN J LYMPHOMA NON-HODGKIN'S CUSTER, GALEN LEUKEMIA; COMPASSIONATE			
		CUTTNER, JANET LEUKEMIA; COMPASSIONATE			
		DANNEMAN, Wm G CA-SOLID; COMPASSIONATE			
		DAO CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS DARA, PARVEZ CA-SOLID; COMPASSIONATE			
		DAVIS, HUGH CA-SOLID; COMPASSIONATE			
		DEAN, HERBERT LEUKEMIA; COMPASSIONATE			

Lead/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		DENEFRIO, JOHN M CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU DENEFRIO, JOHN M CA-SOLID; COMPASSIONATE					
		DENES, ALEX E CA-SOLID; COMPASSIONATE					
		DENHAM, CLAUDE A LEUKEMIA; COMPASSIONATE					
		DESAI, AJIT M LEUKEMIA; COMPASSIONATE					
		DEUR, CHARLES LEUKEMIA; COMPASSIONATE					
		DEUR, CHARLES J CA-SOLID; COMPASSIONATE					
		DICKMAN, ELLIOT CA-SOLID; COMPASSIONATE					
		DOROSHOW CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU DOTY, GORDON L LYMPHOMA; vs m-BACOD m-BNCOD COMBO DOTY, GORDON L CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS DUGAN CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS DeGREEN, PETER LEUKEMIA; COMPASSIONATE					
		ENGELBERG, CHARLES B CA-SOLID; COMPASSIONATE					
		ERSLEV, ALLAN J LEUKEMIA					

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

FEINER, ALAN S
CA-SOLID; COMPASSIONATE

FIELDER, KATHLEEN
CA-SOLID; COMPASSIONATE

FLETCHER, WM
CA-SOLID; COMPASSIONATE

FOOTE, SANDRA
CA-SOLID; COMPASSIONATE

FORTE, FRANCIS A
CA-SOLID; COMPASSIONATE

FORTE, FRANCIS A
LEUKEMIA; COMPASSIONATE

FREDRIC, RHETT K
CA-SOLID; COMPASSIONATE

FRIEDMAN, ALLAN
LEUKEMIA; COMPASSIONATE

GEILS, GEORGE
LEUKEMIA; COMPASSIONATE

GEORGE, SEBASTIAN
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GOCKERMAN, JOHN
LEUKEMIA; COMPASSIONATE

GOODMAN, GARY E
LYMPHOMA; vs m-BACOD
m-BNCOD COMBO
GOODWIN, J WENDALL
CA-SOLID; COMPASSIONATE

GOTTLIEB, ROBERT J
CA-SOLID; COMPASSIONATE

GRACE, WILLIAM R
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
GRACE, WILLIAM R
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMY N-5FU

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		GRACE, WILLIAM R CA-SOLID; COMPASSIONATE			
		GRANATIR, ROBERT LEUKEMIA; COMPASSIONATE			
		GRONCY, PAULA LEUKEMIA; COMPASSIONATE			
		HAN, DIN LEUKEMIA; COMPASSIONATE			
		HANSON, JOHN P LEUKEMIA; COMPASSIONATE			
		HANSON, JOHN P CA-SOLID; COMPASSIONATE			
		HANSON, KARL CA-SOLID; COMPASSIONATE			
		HAROLD, SUSAN E CA-SOLID; COMPASSIONATE			
		HENDERSON, CHARLES A CA-SOLID; COMPASSIONATE			
		HENDERSON, I CRAIG CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS HESKETH, PAUL CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS HOLLAND, JAMES F ALL COMBINED w/ VINCERISTINE & DEXAMETHASONE			
		HOLROYDE, CRISTPHER P LYMPHOMA; vs m-BACOD m-BNCOD COMBO HORVATH, WILLIAM L CA-SOLID; COMPASSIONATE			
		HURD, DAVID CA-SOLID; COMPASSIONATE			
		HYMAN, PAUL CA-SOLID; COMPASSIONATE			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		JAFFREY, IRA S CA-SOLID; COMPASSIONATE			
		JAFFREY, IRA S LYMPHOMA; vs m-BACOD m-BNCOD COMBO JIM, ROBERT T.S. LEUKEMIA; COMPASSIONATE			
		JONES, ROY CA-BREAST; DOSE RANGING ESCALATING DOSE -CARDIAC MEASUREMENTS KAJANI, M LEUKEMIA; COMPASSIONATE			
		KAPLAN, BARRY CA-SOLID; COMPASSIONATE			
		KELSEN, DAVID CA-STOMACH			
		KENNEALEY, GERARD CA-SOLID; COMPASSIONATE			
		KING, GERALD W CA-SOLID; COMPASSIONATE			
		KOO, VICTOR S CA-SOLID; COMPASSIONATE			
		KOWAL-VERN, ARETA LEUKEMIA; COMPASSIONATE			
		KRAKOFF, I H CA-BREAST COMB w/ CYCLOPHOS, 5-FU X-OVER TO ADRIAMYCIN/VINBLASTINE KRAKOFF, I H KREMENTZ, EDWARD T CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS KUBOTA, THOMAS T CA-SOLID; COMPASSIONATE			
		LAWSON CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		LEE, EDWARD LEUKEMIA; COMPASSIONATE			
		LEVICK CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS LEVICK, STANLEY N CA-SOLID; COMPASSIONATE			
		LEVINE, JAMES D LYMPHOMA; vs m-BACOD m-BNCOD COMBO LOCKER, GERSHON CA-SOLID; COMPASSIONATE			
		LOWENBRAUN, STANLEY CA-SOLID; COMPASSIONATE			
		MABRY, R JAMES LYMPHOMA; vs m-BACOD m-BNCOD COMBO MEARS, J GREGORY LEUKEMIA; COMPASSIONATE			
		MENA, PAUL CA-SOLID; COMPASSIONATE			
		MINTON, JOHN CA-SOLID; COMPASSIONATE			
		MOORE, ANN CA-SOLID; COMPASSIONATE			
		MOORE, JOSEPH LEUKEMIA; COMPASSIONATE			
		MOORE, JOSEPH O CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS MORGAN, LEE ROY CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU MUGGIA, FANCO CA-SOLID; COMPASSIONATE			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

MUSS
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
MYERS, ALAN
CA-SOLID; COMPASSIONATE

McFARLAND, JAMES A
LEUKEMIA; COMPASSIONATE

McFARLAND, JAMES A
CA-SOLID; COMPASSIONATE

McKEOWN, JOHN M
CA-SOLID; COMPASSIONATE

McMAHON, RICHARD T
CA-SOLID; COMPASSIONATE

NELSON, ERIC C
CA-SOLID; COMPASSIONATE

NOMANBHOY, YUNUS T
CA-SOLID; COMPASSIONATE

O'CONNELL, JOSEPH
LEUKEMIA; COMPASSIONATE

PANDYA, KISHAN J
CA-SOLID; COMPASSIONATE

PAPISH, STEPHEN W
LEUKEMIA; COMPASSIONATE

PAPISH, STEPHEN W
CA-SOLID; COMPASSIONATE

PARISER, SANFORD
LEUKEMIA; COMPASSIONATE

PAULSON, STEVEN
LEUKEMIA; COMPASSIONATE

PETERSON, JAY T
CA-SOLID; COMPASSIONATE

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

PLOTKIN, DAVID
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PORTLOCK, CAROL S
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
PRESANT, CARY A
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
RIDDICK, DAVID
CA-SOLID; COMPASSIONATE

RIES, CURT
LEUKEMIA; COMPASSIONATE

ROACH, RALPH W
ROBERTS, JOHN
CA-SOLID; COMPASSIONATE

ROEDER, MICHAEL
CA-SOLID; COMPASSIONATE

ROSS
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
ROSS, MICHAEL
CA-SOLID; COMPASSIONATE

ROZEN, SIMON
LEUKEMIA; COMPASSIONATE

RYMER, Wm
CA-SOLID; COMPASSIONATE

SARTIANO, GEORGE P
CA-BREAST; vs ADRIAMYCIN
MULTI-CTR 2nd LINE PTS
SAUNDERS, DARRELL F
LEUKEMIA; COMPASSIONATE

SCHECTER, GERALDINE
LEUKEMIA; COMPASSIONATE

Lead/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		SCHELL,FRANK CJ CA-SOLID; COMPASSIONATE					
		SCHER,NANCY CA-SOLID; COMPASSIONATE					
		SCHREEDER,MARSHALL T CA-SOLID; COMPASSIONATE					
		SCHWARTZ,JOEL CA-SOLID; COMPASSIONATE					
		SEEGER,JARELL CA-SOLID; COMPASSIONATE					
		SENECAL,FRANCIS M LEUKEMIA; COMPASSIONATE					
		SHAW,JOHN LYMPHOMA; vs m-BACOD m-BNCOD COMBO SHERMAN,ALFRED I CA-SOLID; COMPASSIONATE					
		SHIFTAN,THOMAS CA-SOLID; COMPASSIONATE					
		SILVER CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS SILVER,RICHARD T LEUKEMIA; COMPASSIONATE					
		SMITH,FREDERICK P CA-SOLID; COMPASSIONATE					
		STALLINGS,LAWRENCE M CA-SOLID; COMPASSIONATE					
		STASZEWSKI,HARRY LEUKEMIA; COMPASSIONATE					
		STEIN,RICHARD S LYMPHOMA; vs m-BACOD m-BNCOD COMBO STONE,LAWRENCE A LYMPHOMA; vs m-BACOD m-BNCOD COMBO					

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		STRAUSS, JAMES F LEUKEMIA; COMPASSIONATE					
		STUART, JOHN LEUKEMIA; COMPASSIONATE					
		TALARICO, LILIA LEUKEMIA; COMPASSIONATE					
		THOMAS, PAUL LEUKEMIA; COMPASSIONATE					
		VERDIRAME, JOSEPH CA-SOLID; COMPASSIONATE					
		VINCEGUERRA, VINCENT LEUKEMIA; COMPASSIONATE					
		VOGEL, CHARLES CA-SOLID; COMPASSIONATE					
		VOGEL, CHARLES L CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU VOLBERDING CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS					
		VOYCE, GARY F LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		WACHI, DENNIS H LYMPHOMA; vs m-BACOD m-BNCOD COMBO					
		WALLACE, JAMES H CA-SOLID; COMPASSIONATE					
		WEAVER, ZEBULON III CA-SOLID; COMPASSIONATE					
		WEIDEN CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU WEINBERG, BRUCE LEUKEMIA; COMPASSIONATE					

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		WHEELER,R (/GAMS) CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU WHEELER,RICHARD LEUKEMIA			
		WHITE CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS WHITE,CHARLES F CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU WHITE,CHARLES F LYMPHOMA; vs m-BACOD m-BNCOD COMBO WIERNIK,PETER H LYMPHOMA; vs m-BACOD m-BNCOD COMBO WILBUR,DAVID CA-SOLID; COMPASSIONATE			
		WILLIAMS,THOMAS CA-SOLID; COMPASSIONATE			
		WOLF,DAVID LEUKEMIA; COMPASSIONATE			
		WOLFF,STEVEN N CA-BREAST; vs ADRIAMYCIN MULTI-CTR 2nd LINE PTS WOLFF,STEVEN N LYMPHOMA; vs m-BACOD m-BNCOD COMBO WOLFF,STEVEN N CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU WOODCOCK,THOMAS M LYMPHOMA; vs m-BACOD m-BNCOD COMBO WORTMAN,JAMES CA-SOLID; COMPASSIONATE			
		ZALUSKY,RALPH LEUKEMIA; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 92

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		(c) CLINICAL STUDIES PT10b /003-076-000 STATUS OF STUDY DOCUMENTN OF COMPASSION SOLID TUMORS STUDIES					
		(d) CLINICAL STUDIES PT10b /003-077-000 STATUS OF STUDY DOCUMENTN OF COMPASSIONATE LEUKEMIA STUDIES					
L Jul-03-86	T Jul-01-86	CORRESPONDENCE SUMMARY/LISTING OF LOTS USED IN PRESERV-EFF EVALUATION TESTS		GRP			860764
L Jul-15-86		AMENDMENT	86-25	DJF			860668
		(a) INVESTGTR DOCUMENTN AT LEDERLE PT9 /003-076-000 PROT SUBM 1/11/85					
		(b) INVESTGTR DOCUMENTN AT LEDERLE PT9 /003-077-000 PROT SUBM 1/11/85					
L Aug-05-86		AMENDMENT FDA AUTHD TO X-REF OUR IND TO SUPPORT CAPIZZI'S IND FILING	86-26	DJF			870744
L Aug-06-86		AMENDMENT	86-25	DJF			870743
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 LIST OF INVESTGTRs RECEIVING DRUG DURING JULY, '86 BROWN, R.S. CA-SOLID; COMPASSIONATE					
		CARDAMONE, JOSEPH CA-SOLID; COMPASSIONATE					
		HOLLISTER, DICKERMAN LEUKEMIA; COMPASSIONATE					
		LEIBOWITC, R CA-SOLID; COMPASSIONATE					
		LINK, JOHN CA-SOLID; COMPASSIONATE					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 93

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

MUCHMORE, ELAINE
CA-SOLID; COMPASSIONATE

McDONALD, C
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
LIST OF INVSTGTRs RECEIVING DRUG DURING JULY, '86
EYSTER, ELAINE
LEUKEMIA; COMPASSIONATE

KOPEL, SAM
LEUKEMIA; COMPASSIONATE

POLMEROV, T.
LEUKEMIA; COMPASSIONATE

RUBIN, ARNOLD
LEUKEMIA; COMPASSIONATE

SCHARFMAN, WILLIAM
LEUKEMIA; COMPASSIONATE

VONHOFF, DANIEL
LEUKEMIA; COMPASSIONATE

F Aug-11-86	L Jul-03-86	REQUIREMENT	GRP	860720
		(a) PRESERVATIVE EFFICACY LED MUST CLARIFY COMPOSITN/MTD OF MANUF FOR FORMULNS 24E,23R		

L Aug-14-86		AMENDMENT	86-27	DJF	870742
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(a) CKLST
PT9 /003-048-001
CKLST FOR DR. GREEN WHO IS REPLACING MUGGIA AS
PRINC INVSTGR
GREEN, M
CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO)
CYCLOPHOSPHAMIDE-N-5FU vs
CYCLOPHOSPHAMIDE-ADRIAMYCIN-5FU
(b) INVESTIGATOR REPLACEMENT
PT9 /003-048-001
MUGGIA REPLACED BY GREEN

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 94

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		MUGGIA,FRANCO CA-BREAST; vs ADRIAMYCIN (AS PART OF A COMBO) CYCLOPHOSPHAMIDE-N-5FU vs CYCLOPHOSPHAMIDE-ADR IAMYCIN-5FU					
L Aug-18-86	F Aug-11-86	CORRESPONDENCE		GRP			860721
		(a) PRESERVATIVE EFFICACY CLARIFICATION OF COMPOSITION/MANUF'g re PRESERV EFF EVALUATN					
L Sep-02-86		AMENDMENT	86-28	DJF			870702
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 LIST OF INVESTIGATORS RECEIVING DRUG DURING AUGUST, '86 BERNARD,STEPHEN CA-SOLID; COMPASSIONATE					
		BRADY,ALBERT CA-SOLID; COMPASSIONATE					
		CHERNOF,DAVID CA-SOLID; COMPASSIONATE					
		CHLEBOWSKI,JOAN CA-SOLID; COMPASSIONATE					
		FLIPPIN,ANTHONY LEUKEMIA; COMPASSIONATE					
		GRUNDBERG,STEVEN CA-SOLID; COMPASSIONATE					
		MANUSZAK,PAUL CA-SOLID; COMPASSIONATE					
		MILLER,DONALD CA-SOLID; COMPASSIONATE					
		OZA,YAGNESH CA-SOLID; COMPASSIONATE					
		RENTSCHLER,ROBERT CA-SOLID; COMPASSIONATE					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 95

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

SCHNUR, GARY
CA-SOLID; COMPASSIONATE

WORKMAN, FRANK
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
LIST OF INVESTIGATORS REC'g EMERGENCY DRUG SHIPMT
IN AUG. '86
ALLAN, STEVE
LEUKEMIA; COMPASSIONATE

BITRAN, JACOB
LEUKEMIA; COMPASSIONATE

BRASS, LAWRENCE
LEUKEMIA; COMPASSIONATE

KATZ, MARTIN
LEUKEMIA; COMPASSIONATE

KELLERMAYER, ROBERT
LEUKEMIA; COMPASSIONATE

(c) INVESTGTR DOCUMENTN at LEDERLE
PT9 /003-077-000
INVESTIGATOR DOCUMENTN NOW ON FILE (PREVIOUSLY
SHIPPED DRUG)
BURTON, GARY
LEUKEMIA; COMPASSIONATE

MOORE, JOSEPH
LEUKEMIA; COMPASSIONATE

WEINBERG, J
LEUKEMIA; COMPASSIONATE

L Sep-09-86

AMENDMENT

86-29

DJF

860828

(a) CV(& ASSOCs), CKLST, PROT
PT9a,10 /003-084-001
CAPIZZI, ROBERT
LEUKEMIA; VS ARA-C, ASPARAGINASE
MITO IN ANLL, ALL, CBL-BL

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 96

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		(b) CV(& ASSOCs),CKLST,PROT PT9a,10	/003-084-002				
L Oct-01-86		AMENDMENT	86-31	DJF			861028
		(a) CV(& ASSOCs),CKLST PT9	/003-084-003				
		PROT SUBM 9/9/86 RAAB,STEPHEN LEUKEMIA; VS ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL					
L Oct-02-86		AMENDMENT	86-30	DJF			860931
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-115				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 WOZNIAK,ANTIONETTE CA-SOLID; COMPASSIONATE					
		(b) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-116				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 PUGH,REGINALD CA-SOLID; COMPASSIONATE					
		(c) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-117				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 LEWIN,MARGARET CA-SOLID; COMPASSIONATE					
		(e) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-118				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 KRONER,JOAN CA-SOLID; COMPASSIONATE					
		(f) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-119				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 BOHNEN,ROBERT CA-SOLID; COMPASSIONATE					
		(g) INVESTGTR DOCUMENTN at LEDERLE PT9	/003-076-120				
		RECEIVED NOVANTRONE DURING SEPTEMBER, 1986					

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		NICHOLS,CRAIG CA-SOLID; COMPASSIONATE			
		(h) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-121 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 PARKER,BARBARA CA-SOLID; COMPASSIONATE			
		(i) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-122 RECEIVED NOVANTRONE DURING SEPTEMBER, 1986 BROWER,MARTIN CA-SOLID; COMPASSIONATE			
		(j) INVESTGTR DOCUMENTN PENDING PT9 /003-077-070 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING BHARDWHA,SUSHIL LEUKEMIA; COMPASSIONATE			
		(k) INVESTGTR DOCUMENTN PENDING PT9 /003-077-071 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING BEDROSE,ANTRANIK LEUKEMIA; COMPASSIONATE			
		(l) INVESTGTR DOCUMENTN PENDING PT9 /003-077-072 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING CASSILETH,PETER LEUKEMIA; COMPASSIONATE			
		(m) INVESTGTR DOCUMENTN PENDING PT9 /003-077-073 REC'd EMERGENCY DRUG SHIPMENTS 9/86; PROPER DOCUMENTN COMING OLSON,JOHN LEUKEMIA; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 98

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

(a) CV
PT9a /003-082-002
CV FOR LAMB, NEW CO-INVESTIGTR TO SHARIFI; PROT
SUBM 1/10/86
SHARIFI R/ LAMB D
CA-BLADDER; DOSE RANGING
INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd
1/10/86 AS DP3-82
(b) CV
PT9b /003-072-002
CV FOR ALI, NEW CO-INVSTGTR TO CHLEBOWSKI; PROT
SUBM 12/3/83
CHLEBOWSKI/ ALI I
CA-BREAST; SPECIAL-PK
INFLUENCE OF HEPATIC FUNCTION
(c) CV
PT9c /003-046-002
CV FOR MILLER, NEW CO-INVSGTR TO PETERSON; PROT
SUBM 12/8/82
PETERSON / MILLER
LYMPHOMA
NON-HODGKIN'S

L Oct-21-86

CORRESPONDENCE 86-32 DJF 861034
FDA AUTH'd TO X-REF IND pts. 1-6 TO SUPPORT
CHAMPIN'S FILING

L Oct-24-86

AMENDMENT 86-33 DJF 860969

(a) CV(& ASSOCs),CKLST
PT9 /003-084-004
PROT SUBM 9/9/86
TODD, MARY B
LEUKEMIA; vs ARA-C, ASPARAGINASE
MITO IN ANLL, ALL, CBL-BL

L Nov-04-86

AMENDMENT 86-35 DJF 870703

(a) INVESTGTR DOCUMENTN at LEDERLE/003-076-0
LIST OF INVESTIGATORS REC'g DRUG DURING OCTOBER
'86
BROOKS, BARRY
CA-SOLID; COMPASSIONATE

BUTLER, FRED O
CA-SOLID; COMPASSIONATE

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		CARPENTER, JOHN CA-SOLID; COMPASSIONATE			
		HARWIN, WILLIAM CA-SOLID; COMPASSIONATE			
		KISIELIUS, THOMAS CA-SOLID; COMPASSIONATE			
		LYSS, ALAN CA-SOLID; COMPASSIONATE			
		NEEDLES, BURTON M CA-SOLID; COMPASSIONATE			
		RAPHAEL, BRUCE CA-SOLID; COMPASSIONATE			
		SPICER, DARCY CA-SOLID; COMPASSIONATE			
(b)		INVESTGTR DOCUMENTN PENDING PT9 /003-077-000 INVESTIGATORS REC'g EMERGENCY DRUG SHIPMENT DURING OCT. '86 PEMBERTON, CLIFFORD LEUKEMIA; COMPASSIONATE			
		PIETRAGALLO, LOUIS LEUKEMIA; COMPASSIONATE			
		RAGAB, ABDEL LEUKEMIA; COMPASSIONATE			
		SPALDING, MONICA LEUKEMIA; COMPASSIONATE			
(c)		INVESTGTR DOCUMENTN at LEDERLE/003-077-0 INVESTIGATOR DOCUMENTN NOW ON FILE (PREVIOUSLY SHIPPED DRUG) ALLAN, STEVE LEUKEMIA; COMPASSIONATE			
		BRASS, LAWRENCE LEUKEMIA; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 100

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		EYSTER, ELAINE LEUKEMIA; COMPASSIONATE			
		FELBER, NORBERT LEUKEMIA; COMPASSIONATE			
		FLIPPIN, ANTHONY LEUKEMIA; COMPASSIONATE			
		HOLLISTER, DICKERMAN LEUKEMIA; COMPASSIONATE			
		SCHARFMAN, WILLIAM LEUKEMIA; COMPASSIONATE			
		VON HOFF, DANIEL LEUKEMIA; COMPASSIONATE			
L Nov-13-86		AMENDMENT	86-37	DJF	870716
		(a) CV(& ASSOCs), CKLST PT9 /003-082-003 DP 3-82 SUBM 1/13/86 SAROSDY, MICHAEL CA-BLADDER; DOSE RANGING INTRAVESIC ADMIN; DP3-78 REV'd & RESUBM'd 1/10/86 AS DP3-82			
L Nov-25-86		AMENDMENT	86-38	DJF	870722
		(a) PHARMACY BROCHURE # /PT 7 UPDATED PHARMACY BROCHURE (b) DER NARRATIVE PT10 /003-075-001 pts# 31-33,35: DEVELOPED INTESTINAL OBSTRUCT (DOSE-LIM TOX)			
L Dec-05-86		AMENDMENT	86-39	DJF	870730
		(a) INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 RECEIVED EMERGENCY DRUG SHIPMENT DURING NOVEMBER, '86 BERTOLI, JOSEPH CA-SOLID; COMPASSIONATE			

Led/ Event FIA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		CABANILLAS, FERNANDO CA-SOLID; COMPASSIONATE			
		CAMPOS, LUIS CA-SOLID; COMPASSIONATE			
		HILL, LAWRENCE CA-SOLID; COMPASSIONATE			
		POPOVIC, WILLIAM CA-SOLID; COMPASSIONATE			
		SPURR, CHARLES CA-SOLID; COMPASSIONATE			
(b)		INVESTGTR DOCUMENTN PENDING PT9 /003-077-000 RECEIVED EMERGENCY DRUG SHIPMENT DURING NOV. '86 GADUZDA, THOMAS LEUKEMIA; COMPASSIONATE			
		HINES, JOHN LEUKEMIA; COMPASSIONATE			
		HINES, JOHN LICHTMAN, STUART LEUKEMIA; COMPASSIONATE			
		MAZZA, JOSEPH LEUKEMIA; COMPASSIONATE			
		NACHANT, NEIL LEUKEMIA; COMPASSIONATE			
		ROWE, JACOB LEUKEMIA; COMPASSIONATE			
		TISMAN, GLEN LEUKEMIA; COMPASSIONATE			
(c)		INVESTGTR DOCUMENTN at LEDERLE PT9 /003-077-000 DOCUMENTATION NOW ON FILE (PREVIOUSLY SHIPPED DRUG) CAPIZZI, ROBERT LEUKEMIA; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 102

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact Resp ----- Due	Event ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

KELLERMAYER, ROBERT
LEUKEMIA; COMPASSIONATE

(d) DER NARRATIVE
PT10 /003-075-001
11/25/86 DER SHOULD HAVE CITED OVARIAN CANCER AS
INDICATION

L Jan-20-87

AMENDMENT 87-1 DJF 861315
MONTHLY UPDATE FOR DEC '86 OF COMPASSIONATE USE
3-76,3-77

(a) INVESTGTR DOCUMENTN at LEDERLE
PT9 /003-076-000
PROTOCOL 3-76 COMPASSIONATE USE / REC'D DEC 86
AJAIKUMAR, B.S.
CA-SOLID; COMPASSIONATE

FURST, ANNETTE
CA-SOLID; COMPASSIONATE

GEERAERTS, LOUIS
CA-SOLID; COMPASSIONATE

LUEDKE, DAN
CA-SOLID; COMPASSIONATE

LUNDBERG W. BRUCE
CA-SOLID; COMPASSIONATE

PATTON, ALLEN
CA-SOLID; COMPASSIONATE

STASZEWSKI, HARRY
CA-SOLID; COMPASSIONATE

TISMAN, GLENN
CA-SOLID; COMPASSIONATE

(b) INVESTGTR DOCUMENTN PENDING
PT9 /003-077-000
PROTOCOL 3-77 COMPASSIONATE USE
AHMED, FAROUK
LEUKEMIA; COMPASSIONATE

CARTER, PETER
LEUKEMIA; COMPASSIONATE

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOKANTRONE CL-232,315 ANTICANCER AGENT			
		CRAUT, ERIC LEUKEMIA; COMPASSIONATE			
		HYMES, KENNETH LEUKEMIA; COMPASSIONATE			
		JHANGANI, HARESH LEUKEMIA; COMPASSIONATE			
		KLEIN, LEONARD LEUKEMIA; COMPASSIONATE			
		KLEIN, LEONARD LEUKEMIA; COMPASSIONATE			
		KNOSPE, WILLIAM LEUKEMIA; COMPASSIONATE			
		RICHMOND, CAROL LEUKEMIA; COMPASSIONATE			
		STOLBERG, LAWRENCE LEUKEMIA; COMPASSIONATE			
		STOLBERG, LAWRENCE LEUKEMIA; COMPASSIONATE			
		ZEHNGEHOT, LEE LEUKEMIA; COMPASSIONATE			
(c)		INVESTGTR DOCUMENTN at LEDERLE PT9 /003-077-000 PROTOCOL 3-77 COMPASSIONATE USE / REC'D DEC 86 BITRAN, JACOB LEUKEMIA; COMPASSIONATE			
		KATZ, MARTIN LEUKEMIA; COMPASSIONATE			
		RUBIN, ARNOLD LEUKEMIA; COMPASSIONATE			

L Feb-04-87

AMENDMENT

87-2

DJF

861301

(a) CV(& ASSOCs), CKLST
PT9 /003-084-005
PROT SUBMITTED 9/9/86

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 104

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
		STUART, ROBT LEUKEMIA; VS ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL			
I Feb-25-87		AMENDMENT MTHLY UPDATE FOR JAN '87/COMP. USE PROTS 3-76 / 3-77	87-3	DJF	870083
		(a) INVESTGTR DOCUMENTN at LEDERLE # /PT 9 PROT 3-76 COMP USE / REC'D JAN '87			
		(b) INVESTGTR DOCUMENTN PENDING # /PT 9 PROT 3-77 COMPASSIONATE USE			
		(c) INVESTGTR DOCUMENTN at LEDERLE # /PT 9 PROT 3-77 COMPASSIONATE USE / REC'D JAN '87			
I Mar-06-87		AMENDMENT	87-4	DJF	870089
		(a) CV(& ASSOCs),CKLST,PROT PT9, 10 /003-087-001 PROTOCOL #3-87 CHEMO-HORMONAL IN ADV BREAST CA ALLEGRA, JOS. C. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO EPREMIAN, BARBARA E CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO GENTILE, PATRICK S. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO HAMM, JOHN T. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO SEEGER, JANALL CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO			

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT					
		SHETH, SUBHASH P. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO WOODCOCK, THOS, M. CA-BREAST COMB c TAMOX PREMARIN MTX 5-FU LEUCOVORIN CA-BREAST REQUESTED BY DR G.BURKE, MRO					
L Mar-16-87		CORRESPONDENCE FDA AUTH'D TO X-REF IND FOR PATT'S FILING.	87-5	DJF			870979
	(a)	CV PI-YEHUDA PATT PATT, YEHUDA					
L Mar-23-87		AMENDMENT PI- ARNOLD RUBIN	87-6	DJF			870973
	(a)	CV(& ASSOCs) PI- ARNOLD RUBIN TREATNG-ACUTE NONLYMPHOCYTIC LEUKEMIA FERNBACH, BARRY ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) RUBIN, ARNOLD ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE) YAMUSAH, EMANUEL ANLL; vs CERUBIDINE & CYTOSAR (ARA-C) IN COMBO W CYTOSAR (ARA-C)(CYTARABINE)					
L Apr-01-87		CORRESPONDENCE	87-7	DJF			870645
	(a)	PRECLINICAL # /PT 10 NOVANTRONE USED TO TREAT HEPATOCELLULAR CARCINOMA RATAIN, MARK J.					
	(b)	COMPONENTS & COMPOSITION # /PT 10 HEPATOCELLULAR CARCINOMA					
	(c)	CHEMISTRY # /PT 10					
	(d)	MANUF & CONTROLS # /PT 10					
	(e)	CLINICAL STUDIES # /PT 10					

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 106

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT			
L May-14-87		AMENDMENT	87-8	DJF	870637
	(a)	PROTOCOL AMENDMENT PT10 /003-087-001 RADIONUCLIDE SCAN DNE BE4 TREATMNT CYCL WHEN NOV.> 120MG/M2			
L May-22-87		AMENDMENT	87-9	DJF	870635
	(a)	DRUG EXPERIENCE RPT PT10 /003-076-149 OVERDOSE OF NOVANTRONE -FEMALE PAT.-COMP.PROT. BREAST CANCER			
	(b)	PROTOCOL PT10 /003-084-000 STUDY WAS STOPPED DUE TO 2 PATIENTS DEATHS			
	(c)	TRIAL-SITE(S) CLOSED /003-084-0 STUDY 3-84 (ALL SITES 1-5) DISCONTINUED DUE TO DEATHS CAPIZZI,ROBERT LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL HAMPTON,JAMES W LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL RAAB,STEPHEN LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL STUART, ROBERT LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL TODD,MARY B LEUKEMIA; vs ARA-C, ASPARAGINASE MITO IN ANLL, ALL, CBL-BL			
L May-29-87		AMENDMENT	87-10	DJF	870634
		PI- MAURIE MARKMAN-TREATNG OVARIAN CANCER			
	(a)	CV # /PT 9 MARKMAN TREATNG PAT.W/OVARIAN CANCER USING INTRAPERITON.RTE. MARKMAN, MAURIE			
	(a)	CV PI-MAURIE MARKMAN/TREATNG OVARIAN CANCER,INTRAPERITONEAL RT.			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 107

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
16,332	IND	MITOXANTRONE CL 232,315 ANTICANCER AGENT		MARKMAN, MAURIE	
L Jun-03-87		AMENDMENT	87-11	DJF	870633
	(a)	PROTOCOL AMENDMENT PT10 /003-081-001 PHASE II-II STDY W/TNM IN PAT.W/ RECURRENT &METAST.BRST CANC			
L Jun-08-87		AMENDMENT INV/COMP USE	87-12	DJF	870775
	(a)	INVESTGTR DOCUMENTN at LEDERLE PT9 /003-076-000 INV LIST RECD DRUG FROM FEB-MAY '87 (#s 155 THRU 177) BOYLE, EAMONN CA-SOLID; COMPASSIONATE			
		ALLEN EL CA-SOLID; COMPASSIONATE			
		BAGWELL, JOHN CA-SOLID; COMPASSIONATE			
		BROWNE, KENNEDY CA-SOLID; COMPASSIONATE			
		CIMO, PHILIP CA-SOLID; COMPASSIONATE			
		FANGMAN, MICHAEL CA-SOLID; COMPASSIONATE			
		FISHER, JJ CA-SOLID; COMPASSIONATE			
		FORSCHER, CHARLES CA-SOLID; COMPASSIONATE			
		GUY, JERRY T CA-SOLID; COMPASSIONATE			
		HALPERIN, JOSEPH CA-SOLID; COMPASSIONATE			

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 108

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp	Event Due	ID
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16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

HAYWARD, M
CA-SOLID; COMPASSIONATE

HURTUBISE, MICHEL
CA-SOLID; COMPASSIONATE

JENKINS, JAY
CA-SOLID; COMPASSIONATE

KAYE, STEPHEN
CA-SOLID; COMPASSIONATE

MANDEL, EUGENE
CA-SOLID; COMPASSIONATE

MARILLEY, RALPH
CA-SOLID; COMPASSIONATE

MOYNIHAN, J
CA-SOLID; COMPASSIONATE

PRASTHOFER, EDW
CA-SOLID; COMPASSIONATE

RYAN, THOMAS
CA-SOLID; COMPASSIONATE

SAWKAR, LAXMIDAS
CA-SOLID; COMPASSIONATE

SLOAN, M
CA-SOLID; COMPASSIONATE

STINE, ANTHONY
CA-SOLID; COMPASSIONATE

I Jun-30-87

ANNUAL REPORT

87-16

DJF

870962

(a) PROGRESS RPT
86 INV.TREATED 3-76 & 89 TREATED 3-77 SINCE LST
RPT.5/31/86

I Jul-29-87

CORRESPONDENCE

87-15

DJF

870963

FDA AUTH X-REF FOR MARKMAN TO STDY INTRAPERITONEAL

REGULATORY AFFAIRS
DEPT. 956

FDA SUBMISSIONS
SINGLE FDA ID
REPORT 1 - ALL EVENTS -

Feb-17-1988
Page 109

Led/ Event FDA Date	Cross Ref Date	Description	Amendment/ Supplement	Contact	Resp Event ----- Due ID
------------------------	-------------------	-------------	--------------------------	---------	----------------------------

16,332 IND MITOXANTRONE CL 232,315 ANTICANCER AGENT

L Aug-03-87 CORRESPONDENCE 87-19 DJF 871010
DR. JD BITRAN CROSS REF OUR IND/REFRAC METATAST
BREAST CA

L Aug-05-87 AMENDMENT 87-20 DJF 871011
INV / COMP USE

(a) INVESTGTR DOCUMENTN at LEDERLE/003-076-0
INV LIST/COMP USE/JUNE & JULY/#'S 178-185
BOBROW, SAMUEL
CA-SOLID; COMPASSIONATE

EISENBERG, PETER D
CA-SOLID; COMPASSIONATE

GLOWALLA, MICHAEL
CA-SOLID; COMPASSIONATE

KAMPEL, LEWIS
CA-SOLID; COMPASSIONATE

SALTZMAN, MARK
CA-SOLID; COMPASSIONATE

SPITZER, GARY
CA-SOLID; COMPASSIONATE

TIRUMALI, NAGENDRA
CA-SOLID; COMPASSIONATE

YAMAMOTO, KENNETH S
CA-SOLID; COMPASSIONATE

L Aug-07-87 AMENDMENT 87-21 DJF 871004
PROT AMENDMENT #1 / #3-82

(a) PROTOCOL AMENDMENT /003-082-0
PROT #3-82 AMEND OUTLINES DOSE ESCALATION FOR NEW
PATIENTS

L Aug-12-87 AMENDMENT 87-22 DJF 871009
PI-M-MARKMAN TREATING 2ND PT/OVARIAN CA/1ST PT
5/29/87